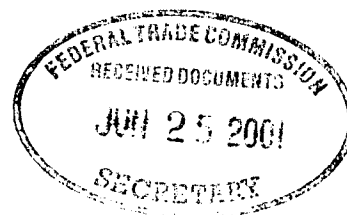


UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION



In the Matter of

SCHERING-PLOUGH CORPORATION,
a corporation,

UPSHER-SMITH LABORATORIES, INC.,
a corporation,

and

AMERICAN HOME PRODUCTS
CORPORATION,
a corporation.

Docket No. 9297

**COMPLAINT COUNSEL'S RESPONSE TO
SCHERING'S MOTION FOR PARTIAL DISMISSAL OF THE COMPLAINT**

Schering has moved to dismiss certain parts of the Commission's complaint on the basis that the complaint fails to make certain allegations. Schering's motion must be denied as the complaint clearly sets forth the basis for an antitrust claim. Moreover, the allegations Schering demands are unnecessary to find that respondents violated the antitrust laws.

The Commission's complaint alleges that respondents entered into unlawful horizontal agreements to delay entry of low-cost generic competition to Schering's highly profitable prescription drug K-Dur 20. (Complaint at ¶ 1). It alleges that Schering has monopoly power in the market that includes K-Dur 20, and that entry of generic competition would significantly erode Schering's market share and profits. *Id.* at ¶¶ 17, 26-30, 37. To protect these profits from the threat of generic competition, Schering conspired with its two potential competitors – Upsher-Smith and AHP – paying them each millions of dollars to delay their entry. *Id.* at ¶¶ 44-5, 55, 57, 64-5.

This conspiracy started when, as part of its patent settlement with Upsher-Smith in June 1997, Schering paid Upsher-Smith \$60 million in return for Upsher-Smith's agreement to stay off the market until 2001. *Id.* at ¶¶ 44, 64-5. This substantial cash payment induced Upsher-Smith to delay launch of its generic product beyond what it would have agreed absent such payments. *Id.* at ¶ 64. Delaying Upsher-Smith in this manner has also delayed entry by other generic manufacturers because of Upsher-Smith's status as the first ANDA filer with rights to 180-days of market exclusivity, based on current law. *Id.* at ¶ 66. Then in January 1998, as part of its patent settlement with AHP, Schering agreed to pay AHP up to \$30 million for AHP's agreement not to compete until 2004. *Id.* at ¶¶ 55, 57, 65. Absent this cash payment, AHP – like Upsher-Smith – would not have agreed to hold back from competing for so long. *Id.* at ¶ 64. By paying off its only two potential competitors at that time, Schering has deprived and continues to deprive consumers of access to a lower-priced generic product. *Id.* at ¶¶ 63-7. As a result of this unlawful conduct, Schering continues to reap (at the expense of consumers) monopoly profits from its \$200 million a year K-Dur franchise. *Id.* at ¶ 32, 67.

Schering has moved to dismiss certain portions of the Commission's complaint on the basis that these allegations fail to state a claim. In Part I of its motion, Schering says that the Commission's allegations that Schering shared monopoly profits with Upsher-Smith and AHP as part of its scheme to avoid generic competition (allegations which must be accepted as true for purposes of this motion) cannot, as a matter of law, make out an antitrust violation because the challenged conduct occurred as a settlement of patent litigation. More specifically, Schering's argument is that its settlements of patent litigation with Upsher-Smith and AHP – no matter the terms nor effect on competition or consumers – could never be a violation of the antitrust laws

unless we allege and this court determines that Schering's patent either is invalid or not infringed. In Part II of its motion, Schering argues that the Commission's allegations about the exclusionary effect of Upsher-Smith's agreement on other potential generic entrants is barred by the Noerr doctrine.

Each of Schering's arguments is without merit and should be denied for the following reasons:

- The Commission's complaint sets forth sufficient allegations of an antitrust claim, and Schering has failed to carry its burden to demonstrate otherwise.
- Allegations concerning the invalidity or non-infringement of Schering's patents and the likely outcome of the patent litigation are not necessary to establish a violation of Section 5 of the FTC Act.
- The exclusionary effect of the Upsher-Smith agreement on other potential generic entrants flows from that agreement and not from any petitioning activity or government action.

For these reasons, Schering's motion for partial dismissal must be denied.

I. The Commission's Complaint Must Include Only a Short and Plain Statement of the Claim Showing That The Commission Is Entitled to Relief.

To prevail on a motion to dismiss for failure to state a claim, respondent must show that the facts alleged by the Commission are insufficient to make a out a violation. *TK-7 Corp.*, 1989 FTC Lexis 32, *3 (1989). For a motion to dismiss, "the factual allegations of the complaint are presumed to be true and all reasonable inferences are to be made in favor of complaint counsel." *Id.* (citing *Miree v. DeKalb County*, 433 U.S. 25, 27 n.2 (1977); *Jenkins v. McKeitchen*, 395 U.S. 411, 421-22 (1969)); *see also Coca-Cola Company*, 1988 FTC Lexis 164, *2.

Moreover, under the Commission's notice pleading standard, *Cliffdale Associates*, FTC Dkt. No. 9156, at 1 (August 28, 1981) (attached as Exhibit A), the complaint "need only give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Quality Foods de Centro America v. Latin American Agribusiness*, 711 F.2d 989, 995 (11 Cir. 1983) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). The complaint "need not plead law or match facts to every element." *Bennett v. Schmidt*, 153 F.3d 516, 518 (7th Cir. 1998). Nor must the complaint allege every fact necessary for finding a violation. *Id.*

Schering's heavy burden, then, is to show that the Commission's complaint failed to provide sufficient information to make clear the substance of the Commission's claims. *See Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 168 (1993); *Carribean Broadcasting Sys., Ltd. v. Cable & Wireless PLC*, 148 F.3d 1080, 1086 (D.C. Cir 1998). Thus, "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which

would entitle him to relief.” *Conley*, 355 U.S. at 45-46. Dismissing a complaint for failing to state a claim, as a practical matter, is appropriate “only in the unusual case in which a plaintiff includes allegations that show on the face of the complaint that there is some insuperable bar to relief.” *Schmedding v. Tnemec Co.*, 187 F.3d 862, 864 (8th Cir. 1999); *Bennett*, 153 F.3d at 519 (“[l]itigants may plead themselves out of court by alleging facts that establish defendants’ entitlement to prevail”).

Schering does not even attempt to meet the motion to dismiss standard. Instead, it would impose – without legal support – a stringent fact pleading requirement. Schering does not argue that a patent settlement can never violate the antitrust laws, nor does Schering argue that the allegations themselves bar recovery. Rather, Schering merely asserts that the complaint should have included allegations about the patent’s invalidity or non-infringement, and the likely outcome of the patent litigation. These are all factual allegations that are neither precluded by the allegations in the complaint nor necessary under a notice pleading system. Accordingly, Schering’s motion must fail for this basic reason. More important, however, is that the allegations Schering demands are irrelevant to proving an antitrust violation.

II. The Commission Complaint Sufficiently Alleges Violations of the Federal Trade Commission Act.

Schering moves for a partial dismissal for failure to state a claim, but does not identify the claim or claims that should be dismissed. By its own admission, every count in the complaint would remain even if the court granted the motion. (Motion at 2, n.1). Rather than explain what substantive violation the complaint fails to allege, Schering demands that the Commission allege certain facts relating to the invalidity or non-infringement of the patent, and

the likely outcome of the patent litigation. However, a finding that the patent was invalid or not infringed is unnecessary to establish a claim under Section 5 of the FTC Act, 15 U.S.C. § 45.

A. Allegations That Schering Paid Upsher-Smith and AHP to Delay Their Entry and Withdraw Their Challenges to Schering's Patent State an Antitrust Claim and Provide a Clear Basis for That Claim.

The Commission's complaint alleges that Schering paid Upsher-Smith and AHP not to compete. (Complaint at ¶¶ 44, 54). Agreements not to compete that unreasonably restrain trade have long been found to violate the antitrust laws. *Northwest Wholesale Stationers, Inc. v. Pacific Stationary & Printing Co.*, 472 U.S. 284, 289-90 (1985) (finding that agreements not to compete are particularly suspect under the antitrust laws, because they "always or almost always tend to restrict competition and decrease output"); *see also Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990) (finding that market allocation "agreements are anticompetitive regardless of whether the parties split a market within which both do business or whether they merely reserve one market for one and another for the other").

Even in the context of patent litigation, agreements by the alleged infringer to stay off the market in exchange for a cash payment from the patent holder have been found to violate the antitrust laws. Just last year, two different federal district courts, in the Hoechst/Andrx and Abbott/Geneva/Zenith decisions,¹ examined agreements like those here that provided for payments from brand-name pharmaceutical companies to their generic competitors to stay off the

¹ *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 682, 706-7 (E.D. Mich. 2000) (concerning the Hoechst/Andrx agreement); *In re Terazosin Hydrochloride Antitrust Litigation*, 2000 U.S. Dist. LEXIS 20477, *6 (S.D. Fla. 2000) (concerning the Abbott/Geneva/Zenith agreement). Both decisions are being appealed. The Commission also challenged the Hoechst/Andrx and Abbott/Geneva agreements, resulting in two separate consent orders. *See In the Matter of Abbott Laboratories*, C-3945, C-3946 (consent order issued May 22, 2000); *In the Matter of Hoechst Marion Roussel, Inc.*, D. 9293 (consent order issued May 5, 2001).

market for some period of time. Each court reached the same basic conclusion: the agreement and payment was “a straightforward horizontal market allocation agreement and thus fits within the category of business practices which have long been held illegal *per se* under section 1 of the Sherman Act.” 105 F. Supp. 2d at 701; *see also* 2000 U.S. Dist. LEXIS 20477, *26 (quoting *U.S. v. Topco Associates, Inc.*, 405 U.S. 596, 608 (1972)) (characterizing the Abbott/Geneva/Zenith agreements as “an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition”). Thus, notwithstanding the patent settlement context, those agreements were such obvious antitrust violations that the respective courts found the agreements to be *per se* violations.²

The Upsher-Smith and AHP settlements harmed consumers by delaying entry of low-priced generic alternatives to Schering’s product. What makes these agreements so effective for respondents is that Schering was a monopolist and that it compensated³ both Upsher-Smith and AHP for a delayed entry. Because Schering was a monopolist, it would lose more from entry

² Schering accurately observes in its motion that the present case is not identical to the Hoechst/Andrx case (Motion at 4), which resulted in a recent consent order between the Commission and those parties. However, this case and the Hoechst/Andrx case share the same fundamental conduct which is the focus of the Commission’s complaint – an agreement under which a brand-name company pays its generic competitor(s) to stay off the market. *See In the Matter of Hoechst Marion Roussel, Inc.*, Analysis to Aid Public Comment, Dkt. No. 9293 (April 2, 2001) (attached as Exhibit B) (“[p]rivate agreements in which the brand name drug company [] pays the first generic to seek FDA approval [], and the ANDA First Filer agrees not to enter the market, have the potential to delay generic competition and raise serious antitrust issues”).

³ The easiest way to compensate a potential entrant to delay entry is with a cash payment or, as alleged here, a cash payment under the veil of a license from the entrant to the incumbent. In theory, the compensation could take many different forms. For simplicity, we refer to compensation as a payment because that is the allegation in this case.

than Upsher-Smith would gain from entry.⁴ Therefore, Schering could pay Upsher-Smith more than Upsher-Smith expected to make if it litigated and prevailed. At the same time, Schering would still be better off than if it lost the patent litigation and faced competition. In addition, as alleged and assumed for purposes of this motion, the payments in each case were for delay and nothing else. Only by compensating the potential entrants can Schering align Upsher-Smith's and AHP's interests with Schering's interest in delaying competition. While Schering and its generic competitors benefitted from the settlements, consumers paid, and are bearing the burden in the form of higher prices. In essence, then, Schering bought-off potential entrants with a share of the monopoly profits, prevented a negative court decision, and obtained a longer monopoly life than it expected to get if it litigated the cases or settled without the payments.

The Upsher-Smith settlement created harm in a second way; it prevented Upsher-Smith from triggering or losing its 180-day exclusivity. If Upsher-Smith had won the litigation, it would have marketed its product and the 180-day exclusivity would have been triggered; if Upsher-Smith had lost, the 180-day exclusivity would have disappeared entirely, thereby removing the barrier to entry for other generic firms. (Complaint at ¶ 47).

By alleging agreements in which Upsher-Smith and AHP agreed to delay entry in exchange for payments, the complaint states a claim actionable under the antitrust laws. In addition to identifying an antitrust claim, the complaint establishes the basis for the claim and provides Schering with adequate notice.

⁴ The patent holder's total profit loss is the per unit profit times the quantity the entrant gains, and the entrant's total gain in profit is its per unit profit times the quantity of its sales. Because the entrant charges a lower price than the patent holder, the patent holder loses more profit than the generic gains. The difference is the benefit consumers gain from increased competition.

B. An Allegation of Invalidity or Non-Infringement Is Not Necessary to Finding Respondents Violated the Antitrust Laws.

Schering contends that complaint counsel must allege that Schering's patent is invalid or not infringed to avoid a dismissal of the complaint. Schering goes further by stating that without such an allegation, the Commission's complaint merely alleges that Schering did something it had an "absolute legal right to do." (Motion at 7). In essence, Schering argues that it can settle a patent dispute on any terms as long as the patent may be valid and infringed.

The allegations that Schering demands are irrelevant to the antitrust analysis here. Schering cites no case law for its proposition that a patent settlement violates the antitrust laws only if the plaintiff can prove that the patent is invalid or that the competitor's product does not infringe. And it does so for good reason: there is no such authority. Quite the opposite, a patent settlement violates the antitrust laws, regardless of invalidity or infringement issues, when the patent-holder entices its competitor to delay entry or withdraw its challenge to the patent in exchange for a share of the monopoly profits. *See United States v. Masonite Corp.*, 316 U.S. 265 (1942). A patent grants its holder the absolute right to refuse to license anyone, and the right to invoke the State's power to prevent others from utilizing a patent-holder's discovery without his consent. *Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 135 (1969). But a patent does not give the patent-holder the unfettered right to bribe its competitors to abandon their competition.⁵

⁵ Schering relies on several cases for the proposition that "a patent holder cannot be held liable under the antitrust laws for enforcing its patent or refusing to license its patent to others." (Motion at 6). Those cases, however, simply demonstrate that certain *unilateral conduct* is lawful under the antitrust laws. *See, e.g., SCM Corp v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d (continued...))

When a patent-holder engages in such conduct – regardless of whether the patent is valid or the conduct arises in the context of patent infringement litigation – it will be held liable under the antitrust laws. In *Masonite*, the patent-holder sued or threatened to sue its competitors for patent infringement. To resolve these disputes, the patent-holder licensed its competitors and potential competitors to sell the patent-holder's product; however, the patent-holder set the price at which its competitors could sell the product. 316 U.S. at 267-373. In deciding the case, the Supreme Court assumed that the patents were valid and that the competitors were trying unsuccessfully to develop non-infringing products. *Id.* at 276, 281-82. Neither fact mattered. The licenses went beyond the legitimate rights of the patent-holder and constituted illegal price-fixing, because the patent-holder enticed its competitors to abandon their own products and their patent challenges in exchange for a share of the monopoly profits. Because competition would reduce everybody's profits, sharing the monopoly profits (through a price fixing agreement) made the parties to the agreements better off than if the competitors were able to successfully challenge the patent or develop around it. As a result of the licenses, "active and vigorous competition then tend[ed] to be impaired not from any preference of the public for the patented product, but from the preference of the competitors for a mutual arrangement – for price-fixing – which promises more profit if the parties abandon rather than maintain competition." *Id.* at 281.

⁵ (...continued)

Cir. 1981) ("a patent holder['s] . . . 'right to exclude . . . ' by refusing unilaterally to license his patent . . . is expressly permitted by the patent laws . . .") (citation omitted) (emphasis added); *Westinghouse Elec. Corp.*, 648 F.2d at 647 ("Westinghouse has done no more than to license some of its patents and refuse to license others"). The present case, however, involves joint agreements by respondents not to compete.

The Supreme Court reached a similar result in *U.S. v. Singer Manufacturing Co.*, 374 U.S. 174 (1963). In that case, the Court considered the patent settlement agreements between Singer and its Swiss and Italian competitors which allowed the parties to avoid a determination on a patent interference pending before the patent office. The parties were concerned that the patent office determination could invalidate their respective patents, thus, leaving them unable to assert those patents against Japanese competitors. By settling this dispute, the patents subject to the interference proceeding issued. *Id.* at 199-200.

On these facts, the Court found a violation of §.1 of the Sherman Act without reaching the substantive issue of whether the patents were in fact invalid. Indeed, the Court specifically recognized that there were multiple possible outcomes of the patent dispute, presumably including a finding that the patents were valid, but still found the agreements unlawful. *Id.* In commenting on this case, Professor Hovenkamp observes the same point:

[A]lthough a declaration of invalidity was a possible outcome of the dispute between Singer and the Swiss firm, it was not the only possible outcome, and *there was no finding by any court or the Patent Office that the patents were in fact invalid.* The crux of the complaint was that by pooling their claims and defending validity jointly against the Japanese, rather than vis-a-vis one another, the defendant and his fellow participants violated the Sherman Act.

11 H. Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION, ¶ 2043 at 240 (1999) (emphasis added); *see also U.S. v. New Wrinkle, Co.*, 342 U.S. 371 (1952) (finding a licensing agreement in violation of the Sherman Act even though the agreement settled a patent interference litigation); *U.S. v. Line Materials Co.*, 333 U.S. 287 (1948) (finding licensing agreements in violation of the Sherman Act without discussing invalidity or infringement).

Similarly, the district courts in Hoechst/Andrx and Abbott/Geneva/Zenith found antitrust violations without determining whether the patents at issue were invalid or not infringed. *In re Terazosin Hydrochloride Antitrust Litigation*, 2000 U.S. Dist. LEXIS 20477, *24 (“[i]nstead of braving the rigors of competition, or unilaterally avoiding the arena, Geneva and Zenith both made pacts with Abbott to ‘enhance their collective profits to the detriment of consumers’” (quoting 7 H. Hovenkamp, ¶ 1503a, at 374); *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d at 701 (“[r]ather than Andrx’s unilateral decisions, the conduct at issue here is Andrx’s bilateral agreement with [Hoechst], its horizontal competitor, that unambiguously allocates the entire market [for the product] . . .”).

Schering argues that proof of invalidity or non-infringement is necessary because otherwise Schering has an absolute right to refuse to license Upsher-Smith or AHP. (Motion at 5). Schering’s right to refuse to license, however, has no significance in this case for three reasons. First, “it will not do to say that since the patentee has the power to refuse a license, he has the lesser power to license on his own conditions.” *Masonite*, 316 U.S. at 277. Schering’s right to refuse to license Upsher-Smith or AHP is far different from allowing Schering to pay Upsher-Smith and AHP in exchange for delayed entry. Second, as *Masonite* and the Hoechst/Andrx and Abbott/Geneva/Zenith court decisions recognize, paying a competitor to delay its entry and abandon its attempts to challenge the patent raise far greater competitive dangers than a refusal to license. Third, when, as alleged here, the patent-holder is a monopolist, it can pay the competitor more than the competitor can earn by successfully challenging the patent. Thus, the patent-holder can prevent successful challenges to the patent and delay competition for a greater length of time than would be expected in litigation.

Schering's position distorts legitimate patent rights – *i.e.*, allowing a patent-holder to exclude others from making, using, or selling the claimed invention – in arguing that the patent-holder can license a competitor on any terms because absolutely barring competitors from the market is worse than competitors selling under a license. If Schering were correct, the Court in *Masonite* and *Singer* would have considered whether any of the competitors' products infringed the patent-holder's patent. Because the question of infringement was not relevant and because the Court explicitly rejected the patent-holder's right to license on any terms, Schering's position contradicts *Masonite* and *Singer*.

The current complaint alleges an antitrust violation that is fully consistent with the prior settlement cases. Not only is it unnecessary for the complaint to allege Schering's patent was invalid or not infringed, proof of invalidity or non-infringement is unnecessary to establish that the settlement agreements violate the antitrust laws.

C. Schering's, Upsher-Smith's, or AHP's Chances of Winning the Patent Suit Are Irrelevant to Determining Whether The Settlement Harmed Competition.

Schering argues that the Commission's complaint must allege the settlement was more anticompetitive than the probable outcome of the litigation (Motion at 7), thereby implying that the complaint must allege the parties' relative chances of winning the patent litigation. As with its argument on the need to allege invalidity or non-infringement, Schering cites no case law to support its position,⁶ and its position contradicts long standing Supreme Court precedent. Just

⁶ Although Schering does cite the Areeda & Hovenkamp treatise in support of its position, it misstates the treatise's position. Schering cites Hovenkamp for the proposition that a settlement is legal if it "is a reasonable accommodation of a bona fide dispute between the

(continued...)

as proof of patent invalidity or non-infringement is unnecessary for proving an antitrust violation in this case, so is proof of the parties' probabilities in winning the patent litigation.

What is required – and is alleged in the Commission's complaint – is that the settlements harmed competition. According to the complaint, the settlement agreements delayed entry of generic competition, and in turn, consumers had to pay the higher monopoly price longer than would have been expected had the parties litigated or settled without a payment.

(Complaint at ¶¶ 66-67). The actual entry date in each settlement, therefore, is later than either a settlement without a payment or the expected result in litigation. Without a payment, AHP and Upsher-Smith would have settled only if they entered earlier than they actually do under the challenged settlements. *Id.* at ¶ 64. By inference, if Schering paid Upsher-Smith \$60 million to delay its entry and paid AHP up to \$30 million to delay its entry, Schering must have bought a better outcome than it expected in litigation (otherwise, Schering would have saved the money and litigated the case).

To make its argument that the allegations in the complaint fall short, Schering goes beyond the complaint and asserts additional facts favorable to its position. First, Schering asserts that “[t]he settlements reflected the parties’ objective chances of success in the underlying

⁶ (...continued)

parties, and ‘is not more anticompetitive than a likely outcome of [the] litigation.’” (Motion at 7). Hovenkamp, in contrast, treats “reasonable accommodation” as a separate element; a settlement is legal if the parties (a) did have a bon fide dispute; and (b) . . . the settlement is a reasonable accommodation *and* is not more anticompetitive than a likely outcome of the litigation.”¹² Hovenkamp, ¶ 2046 at 266 (italics in the original). Patent settlements, like the Schering-Upsher and the Schering-AHP agreements, that violate the long-standing principles in *Masonite*, *Singer*, *New Wrinkle*, and *Line Materials*, are not “reasonable accommodations” of a patent dispute.

lawsuits.” (Motion at 8). However, whether the settlement reflected the parties’ objective chances of success is a fact not in the complaint and contradicted by the allegation that Schering paid Upsher-Smith and AHP to delay their respective entry. Second, Schering alleges that “the ‘but for’ world would have been a continuation of the underlying patent litigation.” *Id.* What would have happened without the payments, however, is a quintessential question of fact. Perhaps the parties would have litigated, or perhaps they would have reached different settlements with earlier entry dates. These facts are irrelevant to whether the complaint states a claim for relief.

III. The Complaint Properly Alleges That Schering’s Agreement with Upsher-Smith Obstructs Entry by Other Potential Generic Entrants.

The complaint alleges that Schering’s agreement with Upsher-Smith served to delay generic competition in two respects. First, Schering’s cash payments under the agreement induced Upsher-Smith to agree to delay launch of its generic product beyond what it would have agreed to absent such payments. (Complaint at ¶ 64). Second, delaying Upsher-Smith in this manner also served to delay entry by any other generic manufacturer, because of Upsher-Smith’s status as the first ANDA filer with rights to 180-days of market exclusivity. *Id.* at ¶ 66. Thus, this single agreement creates both a primary delaying effect on Upsher-Smith’s entry, and a secondary exclusionary effect on all other potential generic entrants.

Schering’s motion contends that this latter allegation of exclusionary effects on third parties is barred by the Noerr doctrine, which protects petitioning for governmental action. This argument not only misconstrues the Noerr doctrine, but also – and more fundamentally – rests on a faulty premise: that any delay of entry by third parties arises solely as a result of the

Hatch-Waxman provisions that award 180-day marketing exclusivity to first filers. In fact, it is the agreement between Schering and Upsher-Smith, and its primary delaying effect on Upsher-Smith's entry, that manipulates the regulatory scheme and thereby triggers the unlawful exclusionary effect identified in the complaint. Finally, Schering's claim that the complaint misstates the law relating to 180-day exclusivity is wrong.

A. The Noerr Doctrine Does Not Apply Here Because the Complaint Does Not Challenge Any Petitioning for Governmental Action.

In essence, the Noerr doctrine provides that parties do not violate the antitrust laws when they seek government action that causes anticompetitive harm. Thus, the antitrust laws do not prohibit collective action aimed at persuading a legislature, administrative agency, or a court to exercise governmental authority in ways that limit competition, even when the parties' aim is anticompetitive.⁷ Ordinarily, the mere petitioning for governmental action by itself does not restrain trade. Only if the petitioning is successful is there a restraint, and in that case it is the governmental action, and not the private conduct, that causes the anticompetitive harm.

The complaint in this case, however, does not challenge any petitioning conduct. Rather, the complaint alleges that Schering agreed to pay Upsher-Smith and AHP millions of dollars in exchange for each competitor staying off the market for a period of time. (Complaint

⁷ *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965); *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972).

at ¶¶ 64-69). Schering's motion for partial dismissal does not even suggest that the challenged agreements amount to a request for governmental action.⁸

Thus, Schering's invocation of the Noerr doctrine in its motion is based entirely on what may be termed its "causation" argument – *i.e.*, its faulty contention that the complaint seeks to impose antitrust liability for anticompetitive effects that are dictated by the Hatch-Waxman Act and the FDA's implementation of the Act. In so doing, Schering misconstrues the scope of Noerr protections. While, as noted above, part of the Noerr analysis often involves an examination of the source of the challenged restraint, the inquiry into the source of the restraint only arises if the conduct at issue amounts to petitioning. Schering cites no case that finds that conduct that is neither petitioning nor conduct "incidental" to petitioning would be protected by the Noerr doctrine.

In sum, the touchstone of the Noerr immunity is the petition for government action. The challenged agreements in this case are not petitioning. Without a challenge to petitioning, there can be no Noerr immunity.

⁸ Schering also has asserted in its answer to the complaint that both of the challenged settlement agreements are immune from antitrust attack under the Noerr doctrine. *See* Seventh Affirmative Defense, Answer at 25. Similar claims to Noerr immunity were rejected by courts considering the Hoechst/Andrx and Abbott/Geneva/Zenith settlement agreements. *See In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d at 633-642; *In re Terazosin Hydrochloride Antitrust Litigation*, 2000 U.S. Dist. LEXIS 20477 at *38-40. The Noerr argument presented in the pending motion for partial dismissal, which is more limited and goes only to Schering's liability for exclusionary effects on third parties arising from its agreement with Upsher-Smith, was not addressed in either of the above cases.

B. The Exclusionary Effects Alleged in the Complaint Stem from the Schering/Upsher-Smith Agreement.

Schering's motion emphasizes that the Hatch-Waxman regulatory scheme, by granting 180-day marketing exclusivity rights to first ANDA filers, gives Upsher-Smith "the ability" to delay competition by other generic firms. (Motion at 4). Schering correctly observes that this ability to block third parties by staying off the market is "a product of federal government decision." *Id.* But this contention is simply beside the point. This case does not challenge either the existence of the 180-day exclusivity period for first generic applicants (which creates Upsher-Smith's ability to delay entry by others), or any unilateral action by Upsher-Smith to exercise rights conferred by Hatch-Waxman.

Instead, the complaint challenges an agreement between competitors, one that displaced unilateral decision-making by Upsher-Smith with a collusive arrangement involving a \$60 million payment in return for which Upsher-Smith agreed to delay its entry into the market. As courts have frequently observed, that a defendant may lawfully do something unilaterally does not mean it may agree with a competitor to take that same action.⁹ Furthermore, the complaint allegation that absent Schering's cash payments under its agreement with Upsher-Smith, Upsher-Smith would not have agreed to delay launch of its generic product for as long as it did (Complaint at ¶ 64), makes it clear that the exclusionary effects on third parties do not arise solely as the result of governmental action, but instead flow directly from the unlawful

⁹ See *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984); *In re Cardizem CD Litigation*, 105 F. Supp. 2d at 648 n.16 ("there are many things a defendant can do unilaterally without offending the antitrust laws that it cannot do collusively"), 658 (Hatch-Waxman Amendments permit certain unilateral action but do not authorize agreements to restrain trade), 663 (same).

agreement. That Upsher-Smith had the ability to cause the same result through lawful unilateral action is irrelevant.¹⁰

Government regulation may erect barriers to entry that serve to create opportunities for anticompetitive behavior. For example, a merger may be unlawful in part because regulatory barriers to entry help to create a likelihood that the merged firm will be able to exercise market power.¹¹ But while governmental action may play a part in creating a party's ability to inflict anticompetitive harm, the governmental action does not "cause" the anticompetitive effects that result from the merger or immunize private anticompetitive conduct from antitrust attack.

C. The Complaint Accurately Describes the Law Concerning the Awarding of 180-Day Marketing Exclusivity Rights.

The competitive harm from the challenged agreements in this case flows in part from an exploitation of the provisions of the Hatch-Waxman Act that award 180-days of marketing exclusivity to the first generic applicant. Schering endeavors to muddy the waters by asserting that the complaint misstates the law governing the exclusivity provision, and by further suggesting that at the time of the agreement it was clear that by settling Upsher-Smith would lose

¹⁰ In addressing causation issues in the context of challenges to a plaintiff's standing to bring suit, courts have frequently observed that the fact that a defendant could have brought about the same result through lawful means does not establish a lack of causation. *See, e.g., In re Brand Name Prescription Drugs Antitrust Litigation*, 186 F.3d 781, 787 (7th Cir. 1999); *Virginia Vermiculite*, 156 F.3d 535, 540 (4th Cir. 1998).

¹¹ *See, e.g., FTC v. University Health, Inc.*, 938 F.2d 1206, 1219-20 (11th Cir. 1991) (noting that Georgia's certificate of need law made concentrated markets more threatening since other firms would not be able to respond to price increases); *U.S. v. Rockford Memorial Corp.*, 898 F.2d 1278, 1285 (7th Cir. 1990) (finding that the regulatory limitations on entry into the hospital industry increase the propensity to collude by preventing entry).

its exclusivity rights, and that Upsher-Smith's current entitlement to exclusivity is in doubt.

(Motion at 10, 12). As we explain below, all these contentions are incorrect. Although the

FDA's implementation of this exclusivity provision has varied over the course of time covered

by the complaint,¹² there are just three basic points about the development of the law concerning the awarding of the 180-day exclusivity period:

- At the time of the Schering's June 1997 agreement with Upsher-Smith, there was some uncertainty about whether Upsher-Smith would retain its right to 180 days of market exclusivity after the settlement.
- The lack of certainty about the awarding of the 180-day exclusivity – and in particular the possibility that Upsher-Smith ultimately might not be deemed entitled to the exclusivity right unless it successfully defended the patent infringement suit brought by Schering – created an incentive for Schering to enter into its January 1998 agreement with AHP.
- Subsequent court decisions eliminated the uncertainty and confirmed Upsher-Smith's right to the 180-day exclusivity period.

¹² Schering repeatedly suggests that there is uncertainty as to whether Congress *intended* first filers who settle to retain exclusivity rights. In fact, however, the cases addressing the exclusivity period turn on the language of the statute, and not any suggestion that Congress intended to permit arrangements like the one challenged here. It has often been observed that settlement agreements like the one challenged here subvert the Congressional intent underlying Hatch-Waxman. *See, e.g.*, 64 Fed. Reg. 42873, 44874-75 (August 8, 1999) (FDA statement regarding proposal for revising Hatch-Waxman regulations notes that agreements forestalling the beginning or triggering of the 180-day exclusivity period "thwart a major Congressional goal underlying the passage of the Hatch-Waxman Amendments"); A. Engleberg, "Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?", 39 J. L. & Tech. 389, 416-17 (1999).

1. The Law on Exclusivity at the Time of the Schering/Upsher-Smith Agreement.

The developments in the law relating to marketing exclusivity for first generic applicants are as follows:

- An FDA rule adopted in 1994 to implement the 180-day market exclusivity provisions of Hatch-Waxman granted exclusivity if the “applicant submitting the first application has successfully defended against a suit for patent infringement.”¹³
- This “successful defense” requirement, however, was under attack and had been challenged in the courts.
- In January 1997, a federal district court in *Mova Pharmaceuticals Corp. v. Shalala*, 955 F. Supp. 128 (D.D.C. 1997), rejected the FDA’s “successful defense” regulation, holding that the 180-day exclusivity period should be granted to the first ANDA applicant regardless of whether the applicant had successfully defended its patent infringement suit.
- Thus, at the time Schering entered into its agreement with Upsher-Smith on June 17, 1997, there was substantial doubt about the continued viability of the FDA’s successful defense requirement.
- Elimination of the successful defense requirement would mean that, if Upsher-Smith settled the infringement suit without an admission that its product infringed, it would continue to be eligible for the 180-day exclusivity period, which would block other generics from coming to market.

Although Schering offers the carefully-worded assertion that “it would have been reasonable for a party, like Schering,” to “assume” that the settlement agreement with Upsher-Smith would deprive Upsher-Smith of its exclusivity rights (Motion at 13), there can be little doubt that

¹³ 59 Fed. Reg. 50338, 50367 (October 3, 1994).

Schering was well aware that there was a substantial likelihood that Upsher-Smith would retain its exclusivity rights after settlement.¹⁴

2. Developments Leading up to Schering's Agreement with AHP.

Between the Upsher-Smith and AHP agreements, developments in the law on exclusivity made it less likely that Upsher-Smith held the 180-day exclusivity.

- In July 1997, another federal district court upheld the FDA's successful defense regulation. *Granutec, Inc. v. Shalala*, 1997 WL 1403894 (E.D.N.C. 1997).
- Following the *Granutec* decision, the FDA issued a statement in November 1997 acknowledging the conflict in the courts and advising that it would apply the successful defense requirement to all ANDAs (whether filed before or after the *Mova* decision) until the appellate courts resolved the issue.¹⁵
- By January 1998, Schering had entered into an agreement in principle with AHP and its patent infringement suit was dismissed.
- The agreement with AHP provided an insurance policy for Schering against generic entry in case the successful defense requirement was ultimately upheld in the courts.

3. Upsher-Smith's Continued Right to the Exclusivity Period Becomes Clear.

- In April 1998, the courts of appeal in *Mova* and *Granutec* held the successful defense requirement invalid.¹⁶

¹⁴ As Schering notes (Motion at 12), the agreement that the Commission challenged involving Hoechst and Andrx also was entered into during this period of uncertainty as to the ultimate fate of the FDA's successful defense requirement. In that matter, the Commission found reason to believe that a violation had occurred.

¹⁵ *Policy on 180-Day Marketing Exclusivity for Drugs Marketed Under Abbreviated New Drug Applications; Clarification*, 62 Fed. Reg. 63268 (November 28, 1997).

¹⁶ *Granutec, Inc. v. Shalala*, No. 97-1874, 1998 U.S. App LEXIS 6685 (4th Cir. 1998); *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir 1998).

- In July 1998, the FDA published a formal statement confirming that it would not enforce a successful defense requirement.¹⁷

The FDA notified Upsher-Smith in March 1997 that it was eligible for the 180-day exclusivity period, has never withdrawn Upsher-Smith's eligibility, and has not granted final approval to any other firm to market a generic version of K-Dur 20 even though AHP long ago received tentative approval. Schering's suggestion that it is unclear whether Upsher-Smith is currently entitled to exclusivity is incorrect. First, Schering points to regulations proposed by the FDA that would affect the triggering of the exclusivity period. These provisions, however, are merely proposals, and in any event would not apply to the Schering/Upsher-Smith settlement agreement. Published almost two years ago, the proposed rules have not become final and there is no indication whether they will take effect in their current form. Moreover, any final rule would apply only to ANDAs pending or filed after the rule's effective date (30 days after the final rule's publication in the Federal Register).¹⁸ Schering's assertion that the proposed regulations "do not conform to the Complaint's version of the FDA law" is simply irrelevant.

Second, Schering discusses at length a letter from the FDA that concluded that Mylan (a first ANDA filer for a generic version of Pfizer's Procardia XL) lost its right to the 180-day exclusivity period after it settled with Pfizer *and* marketed the Pfizer product under a license. The district court, however, affirmed the FDA's decision only on the basis that Mylan was

¹⁷ *Guidance for Industry on 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, 63 Fed. Reg. 37890 (Jul. 14, 1998).

¹⁸ *180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications*, 64 Fed. Reg. 42873, 42882 (Aug. 6, 1999) (proposed rule).

selling a generic product,¹⁹ a fact not present here. The current state of the law, therefore, in no way contradicts the complaint allegations concerning the 180-day exclusivity period or the exclusionary effect of Schering's agreement with Upsher-Smith. More importantly, the fact that the FDA has not granted AHP final approval shows that Upsher-Smith is still entitled to the 180-day exclusivity.

V. Conclusion

For the reasons stated above, complaint counsel respectfully requests that Schering's Motion for Partial Dismissal of the Complaint be denied.

Respectfully submitted,



Karen G. Bokat
Elizabeth Hilder
Michael Kades
Seth C. Silber
Robin Moore
Complaint Counsel

Dated: June 25, 2001

¹⁹ Letter to Deborah A. Taskot, Senior Director, Regulatory Affairs, Teva Pharmaceuticals USA, Inc. from Janet A. Woodcock, Director, Center for Drug Evaluation and Research, FDA (February 6, 2001) (attached as Exhibit D). The FDA concluded (1) that Mylan's decision to settle and not market its product under a license effectively changed Mylan's patent certification from a paragraph IV to a paragraph III and thus rendered Mylan ineligible for the 180-day exclusivity; and (2) that Mylan's exclusivity began to run with its commercial marketing of Pfizer's product. Mylan persuaded a court to reject the first, but not the second, of the FDA's conclusions. *Mylan Pharmaceuticals, Inc. v. Thompson*, No. 1:01CV23 (N.D. W.Va. April 18, 2001) (appeal pending) (attached as Exhibit E).

CERTIFICATE OF SERVICE

I hereby certify that this 25th day of June, 2001, I caused an original, one paper copy and an electronic copy of Complaint Counsel's Response to Schering's Motion for Partial Dismissal of the Complaint to be filed with the Secretary of the Commission, and that two paper copies and an electronic copy were served by hand upon:

Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

and one paper copy was served via facsimile and overnight delivery upon each person listed below:

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Karen G. Bokar

EXHIBIT A

QRF 5 X

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of)	
)	
CLIFFDALE ASSOCIATES, INC.,)	
a corporation,)	DOCKET NO. 9156
JEAN-CLAUDE KOVEN,)	
individually and as an)	
officer of Cliffdale Associates,)	
Inc.,)	
ARTHUR N. SUSSMAN,)	
an individual.)	

ORDER DENYING MOTION FOR MORE DEFINITE STATEMENT

Respondents have filed a motion for more definite statement requesting that complaint counsel (1) be required to identify with more particularity the acts and practices which each respondent is alleged to have committed, and (2) should specify with greater particularity the dates when each of the respondents allegedly committed each of the acts alleged in the complaint. In this respect, respondents point out that the complaint does not state how the individual respondents engaged in the challenged practices. They also assert that the challenged advertisements that were appended to the complaint were disseminated prior to acceptance of a consent agreement by Judge Duvall, an Administrative Law Judge of the United Postal Service, on December 10, 1979.

Complaint counsel has opposed this motion, contending that respondents seek disclosure of evidence in support of the complaint and that such discovery is inappropriate at this stage of the proceeding. Complaint counsel argues that the complaint is legally sufficient to inform the respondents of the nature of the practices challenged in this proceeding. Complaint counsel adds that some post-complaint discovery will be necessary to determine exactly what respondents have done in the recent past.

In my opinion, the complaint satisfies the requirements of "notice" pleading. Respondents' motion indicates that they have sufficient information to file an answer, even if some portion thereof will entail a general denial. Accordingly:

IT IS ORDERED that respondents' motion for more definite statement is denied.

IT IS FURTHER ORDERED that respondents file their answer to the complaint on or before September 10, 1981.

IT IS FURTHER ORDERED that the initial hearing date scheduled to be held September 8, 1981, notice of which was omitted in the original service copy of the complaint, is cancelled.

IT IS FURTHER ORDERED that the parties submit their first discovery requests, if any, to the Administrative Law Judge on or before September 23, 1981. All motions or applications for subpoenas should be filed on the public record.

IT IS FURTHER ORDERED that the parties advise the Administrative Law Judge of a mutually convenient date (and time) during the week of September 28, 1981, on which to hold the prehearing conference required by Section 3.21 of the Commission's Rules of Practice.



Miles J. Brown
Administrative Law Judge

August 28, 1981

EXHIBIT B

Analysis to Aid Public Comment

The Federal Trade Commission has accepted for public comment an agreement and proposed consent order with Hoechst Marion Roussel, Inc. ("HMR"), Carderm Capital, L.P. ("Carderm"), and Andrx Corporation ("Andrx") to resolve the matters alleged in an administrative complaint issued by the Commission on March 16, 2000. The proposed consent order has been placed on the public record for 30 days to receive comments from interested members of the public. The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by HMR, Carderm, or Andrx (collectively "the Respondents") that they violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true. Respondents deny all other allegations of the complaint.

The Complaint

The complaint alleges that the Respondents entered into an agreement that had the tendency or capacity to restrain competition unreasonably by discouraging generic competition to Cardizem CD. Cardizem CD is a prescription drug manufactured and sold by HMR and is used to treat two chronic conditions that affect millions of Americans: hypertension (high blood pressure) and angina pectoris (chest pain). Andrx is a generic drug manufacturer that developed a generic version of Cardizem CD.

Generic drugs typically are sold at substantial discounts from the price of branded drugs. Generic drugs can have a swift marketplace impact, the complaint states, because pharmacists generally are permitted, and in some instances are required, to substitute lower-priced generic drugs for their branded counterparts, unless the prescribing physician directs otherwise. In addition, there is a ready market for generic products because certain third-party payers of prescription drugs (*e.g.*, state Medicaid programs and many private health plans) encourage or insist on the use of generic drugs wherever possible.

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as "the Hatch-Waxman Act," to facilitate the entry of lower priced generic drugs while maintaining incentives to invest in new drug development. A company seeking approval from the Food and Drug Administration ("FDA") to market a new drug must file a New Drug Application ("NDA") demonstrating the safety and efficacy of its product. In order to receive FDA approval to market a generic version of a brand name drug a company must file an Abbreviated New Drug Application ("ANDA") demonstrating that its product is bioequivalent to its brand-name counterpart.

The Hatch-Waxman Act establishes certain rights and procedures in situations where a company seeks FDA approval to market a generic drug prior to the expiration of a patent or patents relating to the brand name drug upon which the generic is based. In such cases, the applicant must: (1) certify to the FDA that the patent in question is invalid or is not infringed by the generic product (known as a "paragraph IV certification"); and (2) notify the patent holder of the filing of the certification. If the holder of the patent rights files a patent infringement suit within 45 days, FDA approval to market the generic drug is automatically stayed for 30 months,

under certain circumstances, unless before that time the patent expires or the patent is judicially determined to be invalid or not infringed. This automatic 30-month stay allows the patent holder time to seek judicial protection of its patent rights before a generic competitor is permitted to market its product.

In addition, the Hatch-Waxman Act provides an incentive for generic drug companies to bear the cost of patent litigation that may arise when they challenge invalid patents or design around valid ones. Under current FDA regulations, the Act grants the first company to file an ANDA with a paragraph IV certification a 180-day period during which it has the exclusive right to market a generic version of the brand name drug. No other generic manufacturer may obtain FDA approval to market its product until the first filer's 180-day exclusivity period has expired. At the time the Respondents entered into the challenged agreement in 1997, the governing FDA regulations required that an ANDA applicant successfully defend the patent holder's patent suit in order to be entitled to this exclusivity.

Andrx was the first company to file an ANDA for a generic version of Cardizem CD. It filed a paragraph IV certification with the FDA stating its belief that the product did not infringe any valid patent covering Cardizem CD. In January 1996, HMR sued Andrx for patent infringement. The lawsuit triggered a 30-month stay of final FDA approval of Andrx's generic product, until July 1998.

According to the complaint, HMR and Andrx entered into an agreement in September 1997, in the midst of this patent lawsuit. At the time of the agreement, approximately nine months before the 30-month stay of FDA approval of Andrx's application would expire, the patent lawsuit had already been pending for twenty-one months and both sides had filed numerous dispositive motions with the trial court that had not been acted on. Also by that time, two other companies, Purepac Pharmaceutical Co. and Biovail Corporation International, had filed for FDA approval of a generic Cardizem CD product, neither of which had yet obtained tentative approval from the FDA.

HMR's forecasts, the complaint states, projected that a generic once-a-day diltiazem product would capture roughly 40 percent of Cardizem CD sales within the first year following its launch. Cardizem CD was HMR's largest selling product at the time. Accordingly, the complaint charges, HMR sought to delay Andrx – and all other potential generic competition to Cardizem CD – from entering the market because of the threat they represented to the high profits it was making from Cardizem CD.

The complaint alleges that on September 24, 1997, HMR, Carderm, and Andrx entered into a "Stipulation and Agreement." The Stipulation and Agreement did not settle the lawsuit. Instead, under this agreement, the complaint alleges that Andrx agreed not to enter the market with its generic Cardizem CD product until the earliest of: (1) final resolution of the patent infringement litigation; (2) Andrx's exercise of an option to obtain a license from HMR in the future; or (3) notice by HMR that it would allow entry of another generic Cardizem CD product

or market its own generic version of Cardizem CD. According to the complaint, Andrx also agreed to refrain from selling during the patent infringement suit any other bioequivalent or generic version of Cardizem CD. In addition, the complaint alleges that Andrx agreed not to withdraw its pending ANDA or to relinquish or otherwise compromise any right accruing under its ANDA, including its 180-day exclusivity right. In return, the complaint alleges, HMR agreed to pay Andrx \$10 million per quarter during the litigation beginning when Andrx received final FDA approval of its ANDA, unless the litigation was resolved prior to that time. Under the agreement, if HMR lost the patent infringement suit it would pay Andrx an additional \$60 million per year for that same time period. On September 25, 1997, the parties made public disclosures of the existence of the agreement. The Commission's complaint alleges that this agreement, at the time it was entered into, had the potential to affect Andrx's incentive to compete once it received final FDA approval.

In July 1998, upon expiration of the 30-month stay under Hatch-Waxman, Andrx received final FDA approval to market its original formulation of generic Cardizem CD that was subject to the still on-going lawsuit with HMR. Pursuant to the terms of the Stipulation and Agreement, HMR began making quarterly payments of \$10 million to Andrx.

Andrx filed a supplement to its ANDA reflecting a reformulation of its generic Cardizem CD product in September 1998. This reformulation altered the dissolution profile of the Andrx product, which was the basis of the patent dispute between Andrx and HMR. The FDA required Andrx to file a new certification and give notice to HMR of the reformulated product under the Hatch-Waxman procedures described above. Following its analysis of the reformulated product, HMR agreed that it would not assert a patent claim against the reformulated product. By June 1999, Andrx had solved the difficulties it had encountered since the summer of 1997 in consistently manufacturing commercial scale quantities of its formulations of its product in conformity with FDA regulations. Andrx received FDA approval in June 1999 to market its reformulated version of Cardizem CD. On or about the day Andrx received FDA approval of its reformulated product, the Respondents entered into a stipulation dismissing the litigation, with an agreement by Andrx not to sell its original formulation and an agreement by HMR not to sue Andrx for patent infringement on Andrx's reformulated product. The challenged agreement terminated.

On or about June 23, 1999, the federal district court dismissed the patent suit, and Andrx commenced marketing its reformulated generic Cardizem CD product, triggering its 180-day exclusivity period. At that time, Biovail Corporation International had not received tentative FDA approval for its product, and Purepac Pharmaceutical Co. had entered into a licensing arrangement with HMR for manufacture of generic Cardizem CD. Andrx's 180-day exclusivity period expired on December 19, 1999. Purepac launched its generic Cardizem CD product the next day pursuant to a license from HMR. Biovail obtained final FDA approval on December 23, 1999, and launched its product shortly thereafter.

Based on the FTC's investigation, it does not appear that there was any delay in the entry into the market of a generic version of Cardizem CD by Andrx or any other potential manufacturer, or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD. The agreement terminated in June 1999. It was at that time that Andrx received FDA approval to market, and commenced marketing, a reformulated generic version of Cardizem CD that HMR stipulated did not infringe any HMR patent.

The complaint alleges that the challenged agreement was not justified by countervailing efficiencies. In its complaint, the Commission alleged that the presence in the agreement of a licensing provision (permitting Andrx to obtain a license from HMR to market generic Cardizem CD in January 2000, in the event Andrx lost the patent litigation, or if another generic company obtained final FDA approval) did not justify the agreement. The complaint alleges that entry by Andrx under a license, had it occurred, likely would have been later than entry by Andrx or another generic manufacturer absent the agreement.

Finally, the complaint charges that HMR had a monopoly in the market for once-a-day diltiazem, and, that by entering into the agreement with Andrx, HMR sought to preserve its dominance by delaying the entry of Andrx and other generic companies into the market. At the time of the challenged agreement, HMR accounted for 70% of the sales of once-a-day diltiazem in the United States. Other drugs, the complaint alleges, are not effective substitutes for once-a-day diltiazem because they are different in efficacy and side effects, and because of risks associated with switching patients from one treatment to another. In addition, the complaint alleges that HMR and Andrx conspired to monopolize the market for once-a-day diltiazem products. The complaint alleges that HMR and Andrx acted with specific intent that HMR monopolize the market for once-a-day diltiazem, and entered into a conspiracy to achieve that goal. Finally, the complaint charges that the Respondents' agreement otherwise amounts to an unfair method of competition in violation of Section 5 of the FTC Act.

The Proposed Order

In a statement issued at the time of the filing of the complaint in this matter, the members of the Commission stated that cases like this one "must be examined with respect to [their] particular facts," and that the "development of a full factual record in the administrative proceeding . . . will help to shape further the appropriate parameters of permissible conduct in this area, and guide other companies and their legal advisors." Although the particular agreement challenged in the complaint has been terminated, the Commission believes prospective relief is necessary to prevent a recurrence of the types of agreements covered by the proposed order. Private agreements in which the brand name drug company (the "NDA Holder") pays the first

¹ Statement of Chairman Pitofsky, Commissioner Anthony, Commissioner Thompson, Commissioner Swindle, and Commissioner Leary concerning Abbott Laboratories and Geneva Pharmaceuticals, Inc., File No. 981-0395 (March 16, 2000).

generic to seek FDA approval (the “ANDA First Filer”), and the ANDA First Filer agrees not to enter the market, have the potential to delay generic competition and raise serious antitrust issues. Moreover, the FDA has observed that the incentives for companies to enter into such arrangements are becoming greater, as the returns to a brand name company from extending its monopoly increasingly exceed the potential economic gains to the generic applicant from its 180 days of market exclusivity.²

The proposed order strikes an appropriate balance, on a prospective basis, between the legitimate interests of the Respondents and the Commission’s concerns with the possible competitive effects of agreements between NDA Holders and ANDA First Filers. By not imposing any broad prohibitions on the Respondents’ ability to compete, the order maintains HMR’s incentive to develop and sell new drug products and Andrx’s incentive to develop and sell generic products that do not infringe valid intellectual property rights held by others. In addition, the order preserves Andrx’s ability to decide for itself whether to market a product in the face of a claim of patent infringement, so long as such decision is otherwise lawful.

As described more fully below, the proposed order:

- bars (except in certain licensing arrangements) two particular types of agreements between brand name drug companies and potential generic competitors – restrictions on giving up Hatch-Waxman 180-day exclusivity rights and on entering the market with a non-infringing product;
- requires that interim settlements of patent litigation involving payments to the generic company in which the generic company temporarily refrains from bringing its generic product to market, be approved by the court, with notice to the Commission to allow it time to present its views to the court; and
- requires the Respondents to give the Commission written notice 30 days before entering into such agreements in other contexts.

Paragraph II prohibits two kinds of agreements between an NDA Holder and the ANDA First Filer (that is, the party possessing an unexpired right to Hatch-Waxman 180-day exclusivity). Paragraph II.A. bars agreements in which the first company to file an ANDA agrees with the NDA Holder not to relinquish its right to the 180-day exclusivity period (as interpreted by the courts at the time of the agreement). Paragraph II.B. prohibits the ANDA First Filer from agreeing not to develop or market a generic drug product that is not the subject of a claim of patent infringement. The order recognizes, however, that even these types of agreements, in the context of certain licensing arrangements, might not raise competitive concerns. Accordingly, conduct otherwise falling within the conduct described in Paragraph II would not be prohibited where the ANDA First Filer agrees to license and introduce a competitive product to the market, its 180-day exclusivity right is not extended, and the Commission is provided notice.

² FDA Proposed Rule Regarding 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873, 42882-83 (August 6, 1999).

Paragraph II's focus on agreements between an NDA Holder and the ANDA First Filer does not mean that the Commission believes that there is no risk of competitive harm in other types of agreements. In particular substantial competitive concerns could arise from an agreement in which a generic company (other than the ANDA First Filer) agrees with the NDA Holder to refrain from marketing a non-infringing product. Given the variety of circumstances in which the restraints may arise, however, and the possibility that some legitimate justifications might exist for such arrangements, the Commission believes that it is appropriate at this time to limit the bans in Paragraph II to the described agreements between NDA Holders and ANDA First Filers.

Paragraph III covers certain private agreements involving payments from the NDA Holder to the ANDA First Filer during patent infringement litigation. Generally, the Respondents can enter into such arrangements only if (a) the agreement is presented to the court and embodied in a court-ordered preliminary injunction, and (b) the following other conditions are met: (i) along with any stipulation for preliminary injunction, Respondents provide the court with a copy of the Commission's complaint, order, and the Analysis to Aid Public Comment in this matter, as well as the proposed agreement; (ii) at least 30 days before submitting the stipulation to the court, they provide written notice (as set forth in Paragraph V of the order) to the Commission; and (iii) they do not oppose Commission participation in the court's consideration of the request for preliminary relief.

This part of the proposed order is designed to enhance the court's ability to assess the competitive implications of such agreements. This remedy, in addition to facilitating the court's access to information about the Commission's views, may also make the process more public and thereby may prompt other generic drug manufacturers (or other interested parties) to participate.

Paragraph IV addresses private agreements in which an ANDA First Filer agrees with the NDA Holder not to enter the market. Such situations would include agreements that are part of a final settlement of the litigation, and situations in which no litigation has been brought. In these circumstances, there may be no judicial role in ordering relief agreed to by the Respondents. Thus, the order requires that the Respondents notify the Commission at least 30 days before entering into such agreements. Such notice will assist the Commission because of the potential for competitive harm that these agreements may create. Absent the order, there may be no effective mechanism for the Commission to find out about such agreements.

The form of notice that the Respondents must provide to the Commission under Paragraphs II, III and IV of the order is set forth in Paragraph V. In addition to supplying a copy of the proposed agreement, the Respondents are required to provide certain other information to assist the Commission in assessing the potential competitive impact of the agreement. Accordingly, the order requires the Respondents to identify, among other things, all others who have filed an ANDA for a product containing the same chemical entities as the product at issue, and the court that is hearing any relevant legal proceedings involving either party. In addition, the

Respondents must provide the Commission with all documents that evaluate the proposed agreement.

The proposed order also contains certain reporting and other provisions that are designed to assist the Commission in monitoring compliance with the order and are standard provisions in Commission orders.

The order will expire in 10 years.

Opportunity for Public Comment

The proposed order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the proposed order and the comments received and will decide whether it should withdraw from the proposed order or make the proposed order final.

By accepting the proposed order subject to final approval, the Commission anticipates that the competitive issues alleged in the complaint will be addressed. The purpose of this analysis is to facilitate public comment on the agreement. It is not intended to constitute an official interpretation of the agreement, the complaint, or the proposed consent order, or to modify their terms in any way.

EXHIBIT C



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

4542 '01 FEB 22 A9:37
Food and Drug Administration
Rockville MD 20857

Deborah A. Jaskot
Senior Director, Regulatory Affairs
Teva Pharmaceuticals USA, Inc.
1510 Delp Drive
Kulpsville, PA 19443

FEB 6 2001

Re: Docket No. 00P-1446/CP1

Dear Ms. Jaskot:

This responds to your citizen petition dated August 9, 2000, requesting the Food and Drug Administration (FDA) to determine (1) that the abbreviated new drug application (ANDA) submitted by Mylan Pharmaceuticals, Inc. (Mylan), for 30-milligram (mg) nifedipine extended-release tablets (ANDA 75-108) is not eligible for 180-day exclusivity or (2) that such exclusivity has expired. Either determination would permit FDA to immediately approve any subsequent ANDA for the same drug. No comments were submitted to the petition docket. For the reasons stated below, your petition is granted.

I. BACKGROUND

The 1984 Drug Price Competition and Patent Term Restoration Act, otherwise known as the Hatch-Waxman Amendments or Hatch-Waxman, includes a provision giving 180 days of marketing exclusivity to the first generic drug applicant to challenge a listed patent for the innovator drug. This provision, found at section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (the statute or Act),¹ has been the subject of considerable litigation and administrative review in recent years, as the courts, industry, and FDA have sought to interpret it in a way that is consistent both with the text and with the legislative goals underlying Hatch-Waxman. A series of federal court decisions beginning with *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1065 (D.C. Cir. 1998), *Granutec, Inc. v. Shalala*, No. 97-1873 and No. 97-1874, 1998 U.S. App. LEXIS 6685 (4th Cir. Apr. 3, 1998), and *Purepac v. Friedman*, 162 F.3d 1201 (D.C. Cir. 1998), and including the recent D.C. Circuit opinion in *Teva Pharmaceuticals USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999) (*Teva I*), describe acceptable interpretations of the 180-day exclusivity provision, identify potential problems in implementing the statute, and establish certain principles to be used by the Agency in interpreting the statute.

In light of court decisions finding certain FDA regulations inconsistent with the statute, the Agency proposed new regulations in August 1999 to implement the 180-day exclusivity. Since that time, many comments have been submitted, and there have been additional court decisions

¹ 21 U.S.C. 355(j)(5)(B)(iv).

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further interpreting the 180-day exclusivity provision. The Agency has not yet published a final rule on 180-day exclusivity. As described in the June 1998 guidance for industry entitled *180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, (1998 Guidance), until new regulations are in place, FDA will address on a case-by-case basis those 180-day exclusivity issues not addressed by the existing regulations. Your petition describes a situation not addressed by FDA's current regulations and thus must be resolved by direct reference to the statute.²

II. THE FACTS

The ANDAs at issue in your petition are for 30-mg extended-release nifedipine tablets. The reference listed drug for these ANDAs is Pfizer's Procardia XL (nifedipine extended-release tablets, 30 mg) (NDA 19-684). At the time ANDAs were submitted for this drug, there were five patents listed for Procardia in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (Orange Book).³ Mylan submitted the first ANDA 75-108 (submitted 4/8/97, received 5/27/97) with a paragraph IV patent certification challenging all five of the listed patents. Other ANDA applicants also submitted certifications challenging the listed patents. As a result of its certification and notice to the NDA holder (Pfizer) and patent owner (Bayer AG), Mylan was sued for patent infringement in the U.S. District Court for the Western District of PA on July 18, 1997. Mylan notified FDA of the filing of this lawsuit, and final approval of the Mylan ANDA was delayed for 30 months. The 30-month stay expired before a decision was rendered in the Mylan/Pfizer patent litigation. FDA gave Mylan final approval to market its 30-mg extended-release nifedipine tablets on December 17, 1999.

Although its ANDA was approved over a year ago, Mylan has not marketed the nifedipine tablets approved in its application. Instead, Mylan announced on March 2, 2000, it had entered into a settlement with Pfizer. The settlement terminated the patent infringement litigation before the district court issued a decision.⁴ Under the terms of the agreement, Mylan obtained a license to market three strengths of Pfizer's extended-release nifedipine tablets, rather than the Mylan product approved by FDA on December 17, 1999. Mylan has not amended its patent certification as a result of the settlement.

² *Teva I* describes FDA's responsibilities in regulating directly from the statute. Specifically, the court cautions that the Agency must explain the basis for its application of the statute, and interpret the statute to avoid absurd results and to further congressional intent (182 F.3d at 1011).

³ U.S. Patent Nos. 5,264,446 (expires 11/23/2010), 4,783,337 (expires 9/16/2003), 4,765,989 (expires 9/16/03), 4,612,008 (expires 9/16/03) and 4,327,725 (expired 11/25/00).

⁴ Shortly after Mylan and Pfizer settled their patent dispute, the patent owner, Bayer AG, and Mylan also settled their dispute, and those claims were dismissed by order entered in 97-CV-1309 on March 22, 2000, in the U.S. District Court for the Western District of PA.

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The question you raise in your petition is whether Mylan is eligible for exclusivity, and if so, whether the exclusivity has already been triggered. If Mylan is eligible for exclusivity and that exclusivity has not begun to run, subsequent applicants will have to wait until the end of exclusivity triggered either by Mylan's marketing or by a court decision in litigation over this drug product finding the patent invalid or not infringed, or until the patent expires. Once the exclusivity has run its 180-day course, subsequent ANDAs may be approved.

You state that because Mylan settled its litigation with Pfizer and is no longer challenging the patent, Mylan no longer qualifies for 180-day exclusivity (Petition at 2). In the alternative, you propose that FDA find Mylan eligible for exclusivity, and that the exclusivity began either on the effective date of the Mylan/Pfizer agreement, or on the date Mylan began to market the licensed nifedipine tablets (*Id.*). As more fully described below, FDA finds that both positions have merit. Under either position, there is no longer a 180-day exclusivity bar to approval of ANDAs for 30-mg extended-release nifedipine tablets.

III. STATUTE AND REGULATIONS

The 180-day generic drug exclusivity provision is one component of the complex patent listing and certification scheme included in the Hatch-Waxman Amendments. These amendments balance the dual goals of encouraging and protecting innovation in drug development and expediting the approval of low-cost generic drugs. The Hatch-Waxman Amendments require innovator companies to submit information on patents claiming the approved drug product (section 505(b)(1) and (c)(2)). FDA publishes this information in the Orange Book. An ANDA must include a patent certification to each patent listed in the Orange Book for the innovator drug. There are four types of patent certification. The two certifications relevant to your petition are a *paragraph III* certification, which seeks approval of the ANDA on the date the patent expires, and a *paragraph IV* certification, which states that the "patent is invalid or will not be infringed by the manufacture, use, or sale of the [drug described in the ANDA]" (section 505(j)(2)(A)(vii)).

The filing of a paragraph IV certification (1) indicates that the ANDA applicant seeks to market its product before the expiration of a listed patent and (2) begins a process in which issues of patent protection may be resolved in patent litigation. The ANDA applicant notifies the NDA holder and patent owner that the ANDA applicant has submitted an ANDA and of the grounds for its belief that the generic drug will not infringe the listed patent(s) (section 505(j)(2)(B)(i) and (ii)). The NDA holder and patent owner then have 45 days to file a suit for patent infringement against the ANDA applicant (section 505(j)(5)(B)(iii)). If such a suit is filed, FDA cannot approve the ANDA for 30 months (or a shorter or longer period ordered by the court) (*Id.*).

The 180-day exclusivity acts as an incentive for the first ANDA applicant to challenge a listed patent. The statutory provision establishing this exclusivity reads:

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If the application contains a [paragraph IV certification] and is for a drug for which a previous application has been submitted under this subsection containing⁵ such a certification, the application shall be made effective not earlier than one hundred eighty days after —

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of the decision of the court in action described in clause (ii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

(section 505(j)(5)(B)(iv))

Only an application containing a paragraph IV certification may be eligible for exclusivity. FDA regulations contain a provision at 21 CFR 314.94(a)(12)(viii) stating that an applicant may amend its patent certification, and if it does so, the application will no longer be considered to contain the previous certification. Under certain circumstances, an ANDA applicant is required to amend its patent certification if the patent is determined to be infringed or if the applicant discovers the submitted certification is no longer correct. If an applicant changes from a paragraph IV certification to a paragraph III certification, the ANDA will no longer be eligible for exclusivity (94 F. Supp.2d at 54-56).

IV. DISCUSSION

In the absence of applicable regulations governing this situation, FDA has interpreted the statute given the facts of this matter and taking into account the purposes of the statute. FDA has determined that Mylan's actions have rendered it ineligible for 180-day exclusivity. Alternatively, FDA has determined that any 180-day period of exclusivity has already expired. Either interpretation leads to the same conclusion — that there is no longer a 180-day exclusivity obstacle to FDA approval of subsequent ANDAs for 30-mg extended-release nifedipine tablets.

The facts in this case are similar to those in *Mylan*, 94 F. Supp.2d at 40-42. In *Mylan*, Barr Laboratories submitted the first ANDA with a paragraph IV certification for the drug tamoxifen. The innovator sued Barr as a result of its paragraph IV certification, and Barr won the case at the district court level. Before an appeal was complete, Barr and the innovator entered into an agreement under which Barr obtained a payment from the innovator and a license to market the innovator's tamoxifen product. The patent infringement litigation was dismissed, and Barr

⁵ The public law version of this provision substituted the word *continuing* for the term *containing*. In *Mylan*, the court determined that such substitution was a "scrivener's error" and "the word 'continuing' was intended to be the word 'containing.'" (*Mylan Pharmaceuticals, Inc. v. Henney*, 94 F. Supp.2d 36 (D.D.C. 2000)).

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certification from a paragraph IV to a paragraph III, and thus Mylan has lost its eligibility for exclusivity.

The generic drug approval provisions of the Act contemplate certain events resulting from the filing of a paragraph IV certification. Once an ANDA applicant notifies the NDA holder and patent owner it is challenging a listed patent, one of two things can happen: either the 45-day period lapses without the filing of a lawsuit and the ANDA can be approved immediately under section 505(j)(5)(B)(iii), or the ANDA applicant is sued for patent infringement and the 30-month stay described in section 505(j)(5)(B)(iii) goes into effect. The statute describes the patent litigation as having two possible results: the court decides the patent is invalid or not infringed, or the court decides the patent has been infringed (section 505(j)(5)(B)(iii)(I)-(III)). The statute provides for court decisions made before or after the 30-month period expires and with or without the approval of the ANDA and marketing of the generic product. But the statute appears to contemplate that there will be a decision on the patent status of the drug and does not identify what to do if the litigation is settled without a court decision on the patent. Because the outcome of patent litigation affects the accuracy of a patent certification and thus eligibility for exclusivity, FDA must determine the effect of this settlement on Mylan's patent certification.⁷

The Mylan/Pfizer settlement resulted in the dismissal of the patent infringement litigation, and in Mylan's marketing of a nifedipine product under a license from Pfizer. Details of the settlement have not been made public, so the agency must rely in making its decision on the limited information that is publicly available and, more importantly, upon the parties' actions. Mylan is no longer participating in litigation intended to prove that its product will not infringe the listed patent.⁸ Moreover, despite the fact that its ANDA has been approved for more than a year, Mylan has never marketed its own ANDA product. These facts lead FDA to presume that Mylan believes the product described in its ANDA may infringe the listed patent and is therefore waiting until patent expiry before marketing its own product. The appropriate certification for a company that has chosen to wait until a listed patent expires before marketing is a paragraph III certification stating the date of patent expiration. Because FDA considers Mylan's actions in settling the litigation and marketing Pfizer's nifedipine product to have effectively changed Mylan's certification from a paragraph IV to a paragraph III, and because applicants who change from a paragraph IV to a paragraph III are no longer eligible for 180-day exclusivity, Mylan has

⁷ The Agency addressed the issue of settlements of patent litigation in the proposed rule and declined to adopt an approach in which ANDA applicants would be required to notify FDA of settlements that would either render the first applicant ineligible for exclusivity or begin the running of exclusivity. Instead, FDA proposed to adopt a triggering period approach. (See 64 FR 42873 at 42880; August 6, 1999.) FDA has not issued final regulations addressing these issues. Therefore, the Agency is relying on a case-by-case approach to particular situations presented and regulating directly from the statute as necessary. FDA's approach to the 180-day exclusivity issues presented in your petition during this interim period should not affect the rulemaking process (*Teva Pharmaceuticals, USA, Inc. v. FDA*, 2000 WL 1838303 (D.C. Cir. 2000)(*Teva II*)).

⁸ This fact alone is not necessarily dispositive on the question of whether — as stated in a paragraph IV certification — the patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which [Mylan's ANDA] was submitted" (section 505(j)(5)(A)(vii)(IV)).

amended its patent certification from a paragraph IV to a paragraph III. The Barr ANDA is not eligible for approval until the patent expires in August 2002. On these facts, the court found two grounds for immediate approval of tamoxifen ANDAs subsequent to Barr. First, the court held that the district court decision, although later vacated, began the running of Barr's exclusivity under section 505(j)(5)(B) (*Id.* at 54). Second, the court found that under FDA's regulation at 21 CFR 314.94(a)(12)(viii) governing amendments to patent certifications, Barr's change from a paragraph IV certification to a paragraph III certification rendered it ineligible for exclusivity (*Id.* at 56-57).

In the course of reaching its decision, the *Mylan* court identified three factors to consider in interpreting the 180-day exclusivity provision of Hatch-Waxman. First, the statute is to be interpreted in a manner consistent with "the statute's interest in affording market access and incentives for both generic and non-generic makers," and to maintain "an incentive for the parties to fulfill the purposes of Hatch-Waxman" (94 F. Supp.2d at 53). Second, FDA should avoid an interpretation that excessively favors the first generic and the innovator parties' "anticompetitive hold" over the drug. The court observed that "Hatch-Waxman intended to provide an incentive for drug companies to explore new drugs, not a market 'windfall' for crafty, albeit industrious, market players" (*Id.*). Finally FDA should avoid interpreting Hatch-Waxman so the decision on whether a generic applicant is entitled to exclusivity rests entirely in the patent holder's hands (*Id.* at 54).

With these principles in mind, the Agency has looked to the statute to determine when subsequent ANDAs for 30-mg extended-release nifedipine tablets may be approved. Specifically, FDA must determine the effect of the dismissal of patent infringement litigation before a court decision and after approval of an ANDA. FDA must also determine whether the marketing of Pfizer's product, in lieu of Mylan's own, has any effect on exclusivity. Under well-established principles of administrative law, FDA has discretion in addressing these questions where the statute does not directly address the issues presented (*Chevron, USA, Inc v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984); *Christensen v. Harris County*, 120 S. Ct. 1655, 1662-63 (2000); 1998 Guidance at 4).

A. Mylan Is No Longer Eligible for Exclusivity

The Agency has reviewed these circumstances and determined that, consistent with the language of the statute, in the absence of an applicable regulation,⁶ and applying the factors identified by the courts in *Mylan* and *Teva I*, the Mylan/Pfizer settlement effectively changed Mylan's patent

⁶ FDA regulations regarding patent certifications do not specifically address the circumstances here. The regulations require an ANDA applicant to change its certification from a paragraph IV to a paragraph III when patent litigation determines the patent is infringed. The regulations also require an applicant to amend its certification if, before the ANDA is approved, the applicant learns that the certification is incorrect. The regulations say nothing about amending a patent certification that becomes inaccurate — other than with a finding of infringement — after an ANDA is approved.

lost its eligibility for exclusivity. This interpretation is consistent with the principles articulated by the *Mylan* court: it avoids perpetuating the first generic and innovator parties' "anti-competitive hold" over the drug and allows market access to other generic manufacturers.

B. Mylan's Exclusivity Started to Run with Its Commercial Marketing of the Innovator's Product.

Alternatively, you ask FDA to consider the "deal" struck by Mylan and Pfizer as "commercial marketing" that begins the running of exclusivity under section 505(j)(5)(B)(iv)(I). According to your interpretation, exclusivity would have begun either on March 2, 2000, the day the settlement was announced, or when Mylan began to market nifedipine under the license from Pfizer. FDA believes a compelling argument can be made that commercial marketing began when Mylan began marketing Pfizer's product. The Chairman, CEO, and President of Mylan noted in the March 2, 2000, press release describing the settlement that "we are pleased with this agreement, which positions Mylan as the first company to offer its customers generic extended-release nifedipine products." Mylan thus believed it was beginning the marketing of a generic drug, which is the event described in the statute as beginning the running of exclusivity.

There are two events that can start the running of exclusivity. As set out above, the exclusivity will begin with the first of either the date of a court decision finding the patent invalid or not infringed or "the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application" (section 505(j)(5)(B)(iv)). One issue for FDA, then, is whether the ANDA applicant's marketing of the innovator's drug as a generic constitutes "commercial marketing of the drug under the previous application." Another consideration is whether such an interpretation would be consistent with the goals of 180-day exclusivity. FDA believes both that Mylan's marketing of the Pfizer drug was commercial marketing that began the exclusivity period and that such an interpretation is fully consistent with the goals of Hatch-Waxman.

FDA's interpretation of the "commercial marketing" trigger is governed by the court's approach to the analogous situation in *Teva I*. In that case, the court looked to the practical effect of the statutory terms in the court decision trigger at section 505(j)(5)(B)(iv)(II) in determining what interpretation was appropriate. The court observed that the term *holding* in that provision was used to describe a court action that has preclusive effect on the innovator's right to pursue a patent infringement action, and because a preclusive finding was contemplated by the statute, a dismissal for lack of subject matter jurisdiction was a court decision triggering the beginning of exclusivity. Any other conclusion would have produced absurd results (182 F.3d at 1009). Similarly, in the present case the Agency has determined that the commercial marketing trigger is intended to give the first ANDA applicant with a paragraph IV certification the opportunity to market a generic version of the innovator's drug with no competition for 180 days. Whether Mylan markets the product approved in its ANDA or the product approved in Pfizer's NDA is of little import to the statutory scheme; Mylan has begun commercial marketing of generic

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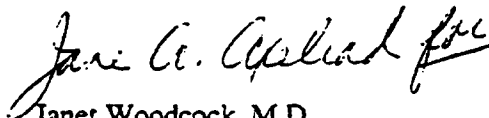
nifedipine. Permitting Mylan to market nifedipine without triggering the beginning of exclusivity would be inconsistent with the intent of the statutory scheme.

Finally, with respect to those Congress intended to benefit, marketing the drug approved in the Pfizer NDA or the drug approved in the Mylan ANDA has the same effect. The benefit intended by the 180-day exclusivity provision is two-fold. First, as is clear in the legislative history, the consuming public is intended to benefit from ANDA approvals through the prompt availability of lower cost generic drugs. Second, ANDA applicants who speed the availability of generic drugs by challenging patents are given the opportunity to reap the economic benefit of limited competition for a period of 180 days. Interpreting Mylan's marketing of the Pfizer product as beginning the running of exclusivity sets a finite limit on the delay in true market competition for this nifedipine product. Moreover, such an interpretation gives Mylan exactly what the statute seemed to intend — 180 days to reap the economic benefits of being Pfizer's sole competition. To permit Mylan to continue to market a nifedipine product without beginning the exclusivity would harm the consuming public by denying access to multiple safe and effective generic nifedipine products ready for final approval. It would also give Mylan (and Pfizer) a windfall clearly not intended by Congress. According to FDA records, Mylan began marketing the 30-mg extended-release nifedipine tablets under the license from Pfizer approximately 10 months ago, on March 28, 2000. Therefore, Mylan has received the full measure of the intended benefit under Hatch-Waxman.

V. CONCLUSION

For the reasons stated above, your petition is granted. Under either of the approaches described, there is no longer a 180-day exclusivity obstacle to FDA approval of subsequent ANDAs for 30-mg extended-release nifedipine tablets.

Sincerely yours,



Janet Woodcock, M.D.

Director

Center for Drug Evaluation and Research

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA



MYLAN PHARMACEUTICALS, INC.,

Plaintiff,

v.

Civil Action No. 1:01CV23
(STAMP)

TOMMY G. THOMPSON, Secretary,
United States Department
of Health and Human Services,
BERNARD A. SCHWETZ, D.V.M., Ph.D.,
Commissioner, U.S. Food
and Drug Administration and
U.S. FOOD AND DRUG ADMINISTRATION,

Defendants.

and

TEVA PHARMACEUTICALS USA, INC.,
BIOVAIL LABORATORIES, INC.,

Intervenors/Defendants.

MEMORANDUM OPINION AND ORDER
DENYING PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION
AND TEMPORARY RESTRAINING ORDER,
DENYING MOTION TO DISMISS OF DEFENDANT
TEVA PHARMACEUTICALS USA, INC. AND
BIOVAIL LABORATORIES, INC. AND
DENYING MOTION OF TEVA PHARMACEUTICALS USA, INC.
AND BIOVAIL LABORATORIES, INC.
FOR EXPEDITED DOCUMENT PRODUCTION

Pending before this Court is the motion of plaintiff Mylan Pharmaceuticals, Inc. ("Mylan") for a preliminary injunction and temporary restraining order filed pursuant to Federal Rule of Civil Procedure 65. For the reasons set forth below and following a hearing on the motion for preliminary injunction held on February 16, 2001, the motion for preliminary injunction and temporary restraining order is denied.

I. Procedural History

Mylan filed a complaint and separate motion for preliminary injunction on February 13, 2001. Following a transfer of this civil action to the undersigned judge, this matter, on February 14, 2001, was set for hearing on February 16, 2001.

On February 13, 2001, Mylan filed a Motion to Shorten Notice Period for Hearing on Temporary Restraining Order and Preliminary Injunction and a separate Motion for Extension of Page Limit, with regard to its Memorandum in Support of its Motion for Preliminary Injunction.

On February 16, 2001, this Court granted Mylan's motion for extension of page limit in regard to Mylan's memorandum in support of its motion for preliminary injunction and also granted the motion of the U.S. Food and Drug Administration ("FDA") for extension of the page limit.

On February 16, 2001, Mylan filed its Memorandum in Support of Motion for Preliminary Injunction, with attached exhibits. At the hearing on February 16, 2001, defendants and intervenors, Teva Pharmaceuticals, USA, Inc. ("Teva") and Biovail Laboratories, Inc. ("Biovail"), filed a joint motion to intervene as defendants which motion, being unopposed, was granted. Teva and Biovail on that date filed their opposition to plaintiff Mylan's motion for a temporary restraining order and preliminary injunction. On February 16, 2001, Teva and Biovail filed the declaration of William S. Marth, Vice President of Sales and Marketing for Teva.

On February 16, 2001, this Court conducted a hearing on the plaintiff's motion for temporary restraining order and preliminary injunction. In addition to the declarations filed by the parties, the Court heard and considered oral argument presented by counsel for all parties.

On February 20, 2001, defendant FDA, Tommy G. Thompson ("Thompson"), and Bernard A. Schwetz, D.V.M., Ph.D., Commissioner of U.S. Food and Drug Administration ("Schwetz"), filed a memorandum in opposition to Mylan's motion for a preliminary injunction. On February 21, 2001, FDA, Thompson, and Schwetz filed a Supplemental Memorandum in Opposition to Mylan's Motion for Preliminary Injunction. On February 21, 2001, Teva and Biovail filed Intervenor's Supplemental Brief Regarding the Adequacy of Any Potential Bond together with their Motion for Leave to File Under Seal Their Supplemental Brief Regarding the Adequacy of Any Potential Bond. On February 21, 2001, intervenors Teva and Biovail filed a motion to dismiss for failure to exhaust administrative remedies and a memorandum in support of that motion. Plaintiff Mylan, on February 21, 2001, filed its Supplementary Memorandum in Support of Its Motion for a Preliminary Injunction on the Issue of Exhaustion.

On February 21, 2001, intervenors Teva and Biovail filed a motion for expedited document production by Mylan. On February 22, 2001, this Court granted intervenors' motion for leave to file their supplemental brief on the adequacy of any bond under seal.

On February 28, 2001, Teva and Biovail filed the declaration, under seal, of Rolf K. Reininghaus in support of the Intervenor's sealed supplemental brief regarding the adequacy of any potential bond. Also on February 28, 2001, Mylan filed the declarations of Dawn Beto and Robert Cunard in support of their motion to shorten the notice period for hearing on preliminary injunction and their motion for preliminary injunction.

II. Factual Background

Plaintiff Mylan is a West Virginia corporation with its principal place of business in Morgantown, West Virginia. Mylan is engaged in the research, development, manufacturing, and distribution of generic pharmaceutical products. Defendant Thompson is Secretary of the U.S. Department of Health and Human Services ("HHS") and is responsible for supervising its activities. Defendant Schwetz is Commissioner of the FDA and is responsible for supervising its activities. Both Thompson and Schwetz are sued in their official capacities. The FDA is an agency within the Public Health Service, which is a part of HHS.

In this civil action, Mylan challenges the FDA's February 6, 2001 decision to grant the Citizen Petition of Teva in which Teva requested that the FDA determine that the Abbreviated New Drug Application ("ANDA") submitted by Mylan for a 30 milligram nifedipine extended release tablet for the treatment of hypertension and angina is not eligible for, or, alternatively, is

no longer eligible for the 180-day exclusivity period provided by certain federal legislation known as the "Hatch-Waxman Amendments."

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman Amendments") amended the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, ~~et seq.~~, ("FFDCA"), which regulates the manufacture and distribution of pharmaceuticals. The stated purpose of the Hatch-Waxman Amendments was to "make available more low cost generic drugs[.]" H.R. Rep. No. 98-857, pt. 1, at 14 (1984). The Hatch-Waxman Amendments created § 505(j) of the FFDCA (21 U.S.C. § 355(j)), and established the Abbreviated New Drug Application ("ANDA") approval process which allows low-priced generic versions of previously approved innovator drugs to be approved and brought to market on an expedited basis. A generic drug contains the same active ingredients as the brand-name counterpart, but does not necessarily contain the same inactive ingredients. See Mova Pharmaceutical Corp. v. Shalala, 140 F.3d 1060, 1063 (D.C. Cir. 1998). Under the Hatch-Waxman Amendments, generic drug makers were permitted to file an ANDA which incorporated data that the "pioneer" manufacturer had already submitted to the FDA regarding the pioneer drug safety and efficacy. In order to obtain FDA approval, the ANDA must demonstrate, among other things, that the generic drug is "bioequivalent" to the pioneer drug. See Mylan v. Shalala, 81 F. Supp. 2d 30, 32 (D.D.C. 2000). As protection for pioneer drug makers, the applicant is also required to certify in

one of four ways that the generic drug will not infringe upon any patent which claims the pioneer drug. See 21 U.S.C. § 355(j)(2)(A)(vii). As Judge Wald noted in Mova Pharmaceutical Corp. v. Shalala:

The Hatch-Waxman Amendments specify the contents of an ANDA in detail. One requirement is that, for each of the patents applicable to the pioneer drug, the ANDA applicant must certify whether the proposed generic drug would infringe that patent, and, if not, why not. The statute provides ANDA applicants with four certification options: they may certify (I) that the required patent information has not been filed; (II) that the patent has expired; (III) that the patent has not expired, but will expire on a particular date; or (IV) that the patent is invalid or will not be infringed by the drug for which the ANDA applicant seeks approval. 21 U.S.C. § 355(j)(2)(A)(vii). We will call these paragraph I, II, III, and IV certifications respectively."

140 F.3d at 1063-64.

This case involves a "IV certification" initially and ultimately, at least according to the FDA, a "III certification."

The Court of Appeals for the Federal Circuit explained the consequences of a "IV certification" as follows:

If the ANDA contains a paragraph IV certification, and all applicable scientific and regulatory requirements have been met, approval of the ANDA "shall be made effective immediately" unless the patent owner brings an action for infringement under 35 U.S.C.A. § 271(e)(2)(A) within forty-five days of receiving the notice required by 21 U.S.C. § 355(j)(2)(B). 21 U.S.C. § 355(j)(4)(B)(iii). The Hatch-Waxman Act further provides that, when a patent owner brings a section 271(e)(2)(A) infringement action, the FDA must suspend approval of the ANDA. Id. The suspension continues -- and the FDA cannot approve the ANDA -- until the earliest of three dates: (i) if the court decides that the patent is invalid or not infringed, the date of the court's decision; (ii) if the court decides that the patent has been infringed, the date that the patent expires; or (iii) subject to modification by the court, the date that

is thirty months from the patent owner's receipt of the notice of the filing of the paragraph IV certification. 21 U.S.C. § 355(j)(4)(B)(iii)(I)-(III); 35 U.S.C.A. § 271(e)(4)(A).

Bristol-Myers Squibb Co. v. Royce Lab., 69 F.3d 1130, 1131-32 (Fed. Cir. 1995), cert. denied, 516 U.S. 1026 (1995); see also Mova, 140 F.3d at 1064.

The statute provides that if an ANDA contains a "IV certification" and is for a drug for which a previous ANDA has been submitted containing such a certification, the later application shall be made effective not earlier than 180 days after the earlier of: (1) the date the FDA received notice from the first ANDA applicant of the first commercial marketing of the drug, or (2) the date of decision of a court in a patent infringement action holding the patent which is the subject of the certification to be invalid or not infringed. This particular provision provides an advantage to the first entity seeking to market a generic version of an already approved drug to undertake a challenge to the patent (or patents) blocking generic competition with respect to that already approved drug. See Compl. at ¶¶ 11 and 12.

Pfizer, Inc. ("Pfizer") is the holder of an approved New Drug Application ("NDA") for nifedipine tablets, extended release, which it has sold since 1990 under the brand name Procardia® XL. Pfizer has patented this product and the patent was subsequently listed by the FDA in the Orange Book¹ under that product. Procardia® XL is

¹ Approved Drug Products with Therapeutic Equivalence Evaluations

sold exclusively by Pfizer for three available strengths (30, 60 and 90 mg). In April 1997, Mylan became the first generic manufacturer to file an ANDA directed towards a nifedipine tablet which is a generic bioequivalent of the 30 mg extended release Procardia® XL tablet. Mylan's ANDA contained a "IV certification" with respect to the Pfizer patent.

Thereafter, Pfizer filed a civil action against Mylan in the United States District Court for the Western District of Pennsylvania for infringement of its patent. On February 28, 2000, Pfizer and Mylan entered into a settlement agreement which, according to Mylan's complaint, (a) stipulated to the dismissal of the Pfizer-Mylan civil action, (b) granted Mylan a license to sell a private label version of 30, 60 and 90 milligram Procardia® XL nifedipine extended release tablet supplied by Pfizer, and (c) permitted Mylan to market its own 30 milligram ANDA product. Mylan asserts that had the patent civil action in the Western District of Pennsylvania been tried and had Mylan prevailed in that civil action, then Mylan would only have been entitled to market the 30 milligram nifedipine extended release product covered by its own ANDA. Pursuant to the settlement agreement, the civil action in the Western District of Pennsylvania was dismissed without prejudice and Mylan maintained its "IV certification" for its ANDA. See Compl. at ¶¶ 14, 15, 16, 17, 18 and 19. The above-mentioned settlement agreement has not been attached to any papers filed by Mylan in this civil action and has not, as of this date, otherwise

been submitted in this civil action, despite defendants' request that it do so.

On April 28, 2000, several months after the Pfizer-Mylan settlement, Mylan received a letter from Biovail asking that Mylan waive its 180-day exclusivity period under the Hatch-Waxman Amendments. On May 4, 2000, Mylan responded that it was prepared to entertain a reasonable offer from Biovail with respect to its exclusivity rights. Biovail responded to that letter on May 29, 2000 but did not make any offer with respect to Mylan's exclusivity. On July 21, 2000, Mylan wrote to Biovail to repeat its invitation to Biovail to submit an offer with respect to Mylan's exclusivity rights. Biovail did not respond to that letter. See Compl. at ¶¶ 20, 21, 22, 23 and 24.

On August 10, 2000, Teva, a licensee of Biovail, filed a Citizen Petition with the FDA in which Teva requested that the FDA determine that the ANDA submitted by Mylan for a 30 milligram nifedipine extended release tablet for the treatment of hypertension and angina was not eligible for or, alternatively, is no longer eligible for the 180-day exclusivity period provided by the Hatch-Waxman Amendments and that the FDA approve the ANDA of Biovail for a 30 milligram extended release nifedipine tablet. The FDA granted Teva's Citizen Petition on February 6, 2001. That decision is attached to and made a part of Biovail's opposition to plaintiff Mylan's motion for a temporary restraining order and preliminary injunction. By this decision, the FDA granted Teva's

Citizen Petition on two grounds. First, the FDA held that as a result of the settlement that Mylan reached with Pfizer (the NDA holder and patent owner) whereby Pfizer dismissed its patent infringement suit in the Western District of Pennsylvania, and also whereby Mylan entered into a licensing agreement with Pfizer to market a private label generic version of Pfizer's Procardia® XL nifedipine extended release product, Mylan's "IV certification" under the statute was "effectively changed" from a "IV certification" to a "III certification." Therefore, because applicants who change from a "IV certification" to a "III certification" are no longer eligible for the 180-day exclusivity, the FDA held that Mylan lost its eligibility for exclusivity. Second, the FDA held that Mylan, by marketing its private label generic version of Pfizer's Procardia® XL product, as opposed to its own 30 milligram ANDA product, triggered the "commercial marketing" provision of 21 U.S.C. § 355(j)(5)(B)(iv)(I) thereby commencing the running of the 180-day exclusivity period.

The February 6, 2001 decision of the FDA was issued after Teva and Biovail had filed a civil action against the FDA in the United States District Court for the District of Columbia, and had moved for summary judgment. The FDA's February 6, 2001 decision was issued before its response to Teva's motion for summary judgment was due, thereby rendering moot the civil action filed by Teva. The Teva and Biovail-FDA civil action was then dismissed.

The FDA by its February 6, 2001 decision approved Biovail's ANDA thereby allowing Teva to market Biovail's 30 milligram extended release generic version of Procardia® XL. See Compl. at ¶¶ 1-4. As the FDA explained in its February 6, 2001 decision, existing FDA regulations did not cover the factual situation presented in the Citizen Petition. Instead, the FDA decision was governed by a what is termed a "guidance document" that provides that, until new FDA regulations are in place, the FDA will address any 180-day exclusivity issue not addressed by existing FDA regulations on a case-by-case basis. See "180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act" (1998 Guidance), attached as Tab 1 to Memorandum in Opposition to Mylan's Motion for a preliminary Injunction filed by defendants FDA, Thompson and Schwetz. On February 9, 2000, Teva began shipping the Biovail 30 milligram generic nifedipine product to its wholesale and retail outlets.

In this civil action, Mylan contends that the FDA's granting of the Teva Citizens Petition was arbitrary and capricious. Mylan requests that this Court enjoin Biovail's approved status which would have the affect of reinstating Mylan as the sole generic drug on the market. Mylan contends that its 180-day exclusivity period under its ANDA has not yet been "triggered" by either provision of 21 U.S.C. § 355(j)(5)(B)(iv) so as to begin to run. Mylan further alleges that the FDA's conclusion that Mylan's ANDA certification was "effectively changed" from a "IV certification" to a "III

certification" as a result of its settlement agreement with Pfizer and licensing for sale of a private label generic version of Procardia® XL products, thus rendering it ineligible for the 180-day exclusivity period, is contrary to law and is arbitrary and capricious because, according to Mylan, the FDA's conclusion is not based upon any reasonable construction of the language of the Hatch-Waxman Amendments or upon any specific factual findings with respect to the settlement agreement in terms of the license. Mylan also contends that the FDA ruling that the 180-day exclusivity period for Mylan's ANDA began to run from the date that Mylan began marketing the private label generic version of Procardia® XL nifedipine products under a license with Pfizer is also contrary to law and is arbitrary and capricious because, as with the first ruling, the FDA's conclusion is not based on any reasonable construction of the language of the Hatch Waxman Amendments or on any specific factual findings with respect to the settlement agreement and terms of the license. Specifically, at this stage of the case, Mylan claims that it is entitled to injunctive relief that requires the defendants FDA, Thompson and Schwetz to withdraw approval of Biovail's ANDA and to notify Biovail that the approval of its ANDA cannot be made effective until the end of Mylan's 180-day exclusivity period.

III. Applicable Law

The Fourth Circuit recognizes that "preliminary injunctions are extraordinary remedies involving the exercise of a very far-reaching power to be granted only sparingly and in limited circumstances." MicroStrategy Inc. v. Motorola Inc., No. 01-1289, 2001 WL 293602, at *2 (4th Cir. Mar. 28, 2001) (quoting Direx Israel, Ltd. v. Breakthrough Med. Corp., 952 F.2d 802, 816 (4th Cir. 1992)) (internal quotation marks omitted).

In Blackwelder Furniture Co. v. Seilig Mfg. Co., Inc., 550 F.2d 189 (4th Cir. 1977), Rum Creek Coal Sales, Inc. v. Caperton, 826 F.2d 353 (4th Cir. 1991) and Direx Israel, Ltd. v. Breakthrough Medical Corp., 952 F.2d 802 (4th Cir. 1991), the Fourth Circuit has set forth the equitable factors that a district court must consider when determining whether a temporary restraining order or preliminary injunction should issue. See also C/R TV Cable, Inc. v. Shannondale, Inc., 792 F. Supp. 1018, 1021-22 (N.D. W. Va. 1992). The four factors which must be considered in granting the preliminary injunction under the Fourth Circuit test are:

- (1) the likelihood of irreparable harm to the plaintiff if the preliminary injunction is denied, (2) the likelihood of harm to the defendant if the requested relief is granted, (3) the likelihood that the plaintiff will succeed on the merits, and (4) the public interest.

Direx Israel, 952 F.2d at 812 (citing Rum Creek, 926 F.2d at 859). Additionally, the "[p]laintiff bears the burden of establishing that each of these factors supports granting the injunction." Id.

(quoting Technical Publishing Co. v. Lebhar-Friedman, Inc., 729 F.2d 1136, 1139 (7th Cir. 1984)).

The Direx Israel court emphasized that "[t]he 'likelihood of irreparable harm to the plaintiff' is the first factor to be considered in this connection." Id. If the plaintiff makes "a 'clear showing' of irreparable injury absent preliminary injunctive relief," a district court must then balance the likelihood of irreparable harm to the plaintiff without an injunction against the likelihood of harm to the defendant with an injunction. Id.; Blackwelder, 550 F.2d at 195. Then, if a decided imbalance of hardship appears in the plaintiff's favor, the plaintiff need not show a likelihood of success; plaintiff need only show that grave or serious questions are presented by plaintiff's claim. Id. at 195-96; see also James A. Merritt & Sons v. Marsh, 791 F.2d 328, 330 (4th Cir. 1986) ("When the balance of harms decidedly favors the plaintiff, he is not required to make a strong showing of a likelihood of success"). The district court should also consider the public interest. Blackwelder, 550 F.2d at 196. However, as the Blackwelder court concluded "[t]he two more important factors are those of probable irreparable injury to plaintiff without a decree and of likely harm to the defendant with the decree." Id.

The issuance of a preliminary injunction is committed to the sound discretion of the district court. Conservation Council of North Carolina v. Costanzo, 550 F.2d 498, 502 (4th Cir. 1974). In

deciding whether to issue a temporary restraining order, the factors to be weighed are the same as those to be weighed in deciding whether to enter a preliminary injunction, Commonwealth of Virginia v. Kelly, 29 F.3d 145, 147 (4th Cir. 1994). If a preliminary injunction is granted, the order granting same must "set forth the reasons for its issuance; shall be specific in terms; [and] shall describe in reasonable detail, and not by reference to the complaint or other document, the act or acts to be restrained." See Fed. R. Civ. P. 65(d); Fed. R. Civ. P. 52(a) ("[I]n granting or refusing interlocutory injunctions the court shall . . . set forth the findings of fact and conclusions of law which constitute the grounds of its action.").

IV. Injunctive Relief

A. Irreparable Harm to Mylan

First, Mylan must establish that it is likely to suffer irreparable harm if injunctive relief is not granted. See Direrex Israel, 952 F.2d at 812. Irreparable harm to Mylan must be actual and imminent, not remote and speculative. As the court noted in Direrex Israel:

The hardship balance and the likelihood of success determination are separate, sequential steps in the application of the hardship test. [Blackwelder Furniture Co. of Statesville, Inc. v. Seilig Mfg. Co., 550 F.2d 189 (4th Cir. 1977)] makes it plain that the balancing of hardship should proceed any consideration of the likelihood of success And the reason for this statement is easy to understand. The hardship test, by its very nature, is to proceed the consideration of the likelihood of success, since the outcome of the hardship test fixes the degree of proof required for establishing the likelihood of success by the plaintiff. If the

hardship balance tilts sharply and clearly in the plaintiff's favor, the required proof of likelihood of success is substantively reduced. Similarly, if the hardship to plaintiff is minimal or nonexistent . . . then the burden on the plaintiff to establish likelihood of success on the merits becomes considerably greater. The likelihood of success determination is to proceed only after the hardship balance itself had been resolved. It is obvious error to resolve the hardship test by including it in the likelihood-of-success test.

Id. at 817 (emphasis added).

Mylan, referring to the Declaration of its Vice President of Marketing, Robert Cunard, asserts that if Mylan loses its 180-day exclusivity, Cunard "believe[s] Mylan will lose at least 30% of the generic 30 milligram nifedipine extended release market to Biovail." Cunard also "believe[s] that as a result of this lost market share and price competition with Biovail, Mylan will irretrievably lose over ten million dollars in sales revenues and several million dollars in profits over a 180-day period following the launch of Biovail's 30 milligram nifedipine extended release product." Cunard Declaration at ¶ 11.

Further, Cunard's Declaration states that "Mylan's irretrievable losses [sic] would not be limited to its 30 mg nifedipine product. Purchasers of pharmaceutical products generally prefer to buy pharmaceutical products from a company that can supply multiple strengths of a given product Because Biovail has been on a market with a generic 60 milligram nifedipine product since September 2000, Biovail will now be able to supply both the 30 and 60 milligram nifedipine extended release products, which are the two most popular strengths." Therefore, states

Cunard, Mylan will lose significant market share not only for its 30 milligram nifedipine, but also on its 60 milligram nifedipine extended release product, and that "a significant number of Mylan's customers will likely switch" to purchasing Biovail's 30 and 60 milligram product because of "the preference to purchase different dosage strength versions of a pharmaceutical product from the same supplies." Cunard Declaration at ¶ 12.

The defendants maintain that Mylan cannot show irreparable harm simply through its belief or expectation that it will or may sustain lost sales revenue. Courts in another jurisdiction in which Mylan has sought injunctive relief have held that purely economic injury and economic loss alone, however substantial, does not constitute irreparable harm. Mylan v. Henney, 94 F. Supp. 2d 36, 58 (D.D.C. 2000); Mylan v. Shalala, 81 F. Supp. 2d 30, 42 (D. D.C. 2000). In any event, the required "irreparable harm" must be "neither remote nor speculative, but actual and imminent." Direx Israel, Ltd., 952 F.2d at 812. The plaintiff must make a "clear showing" of irreparable harm. See id. (quoting ECRI v. McGraw Hill, Inc., 809 F.2d 223, 226 (3d Cir. 1987)) ("Establishing a risk of irreparable harm is not enough. A plaintiff has the burden of proving a 'clear showing of immediate irreparable injury.'") As any injury must be such that it cannot be fully remedied by an award of monetary damages, courts have been hesitant to award injunctive relief based on assertions of lost opportunities and market share.

Mylan v. Kenney, 94 F. Supp. 2d at 58; Mylan v. Shalala, 817 F. Supp. 2d at 42.

B. Irreparable Harm to Defendants

Looking at the second factor under the Blackwelder analysis, i.e., the likelihood of harm to the defendants if the request is granted, defendants Biovail and Teva contend that if injunctive relief is granted, and Biovail is not permitted to continue to market its product, both Biovail and Teva will also lose substantial sums of money. In his Declaration, filed as Exhibit 6 to Teva and Biovail's Opposition to Mylan's Motion for a Temporary Restraining Order and a Preliminary Injunction, William S. Marth indicates that Teva, as of February 15, 2001, has pending orders worth \$10 million which it is in the process of filling. Marth makes a "conservative" estimate that over the next several months, Teva will lose approximately \$125,266.00 per day with lost revenues over a six-month period of \$22,550,000.00

Hence, Mylan, Teva and Biovail allege similar economic injuries. However, "if 'the plight of the defendant [is] not substantially different from that of the plaintiffs; that is, if there is no imbalance of hardship in favor of the plaintiff, then 'the probability of success begins to assume real significance,' and interim relief is more likely to require a clear showing of a likelihood of success." Direx Israel, 952 F.2d at 808 (quoting Blackwelder, 550 F.2d at 195 n.3). Similarly, the FDA maintains that it would be harmed by "the Court's sanctioning of Mylan's

continued monopoly and by the disruption of the FDA's generic drug program." Memorandum in Opposition to Mylan's Motion for a Preliminary Injunction at 29.

At this point, this Court believes that the balance of hardship to Mylan "does not tilt decidedly in plaintiff's favor," and that, therefore, plaintiff Mylan must demonstrate a "strong showing of likelihood of success" or a "substantial likelihood of success" by "clear and convincing evidence" in order to obtain injunctive relief. Direx Israel, Ltd., 952 F.2d at 818.

C. Likelihood of Success

Under the Administrative Procedures Act, the decisions of the FDA are subject to judicial review and will only be overturned if they are arbitrary and capricious. 5 U.S.C. § 706. The standard of review for courts examining agency decisions is set forth in Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). The Fourth Circuit recently discussed the test under Chevron in America Online v. AT&T Corp., No. 99-2138, 2001 WL 197818, at *24 (4th Cir. Feb. 28, 2001), as follows:

Chevron . . . directs a court, when reviewing an agency's interpretation of a statute, to engage in a two-step process. First, it must determine "whether Congress has directly spoken to the precise question at issue." Only if the statutory language is silent or ambiguous with respect to the question posed does the court then proceed to the second step -- to determine "whether the agency's answer is based on a permissible construction of the statute." . . . Thus, Chevron deference is a tool of statutory construction whereby courts are instructed to defer to the reasonable interpretation of expert agencies charged by Congress "to fill any gap left, implicitly or explicitly," in the statutes they administer.

1. FDA Conversion of "IV Certification" to "III Certification"

The FDA, in its February 6, 2001 ruling on the Citizen Petition of Teva, found that Mylan would no longer be eligible for the 180-day exclusivity. After reviewing the Pfizer-Mylan litigation, the FDA ruled that the settlement of that civil action "effectively changed" Mylan's patent certification from a paragraph IV to a paragraph III, and thus Mylan has lost its eligibility for exclusivity. The FDA acknowledges that it has "not yet published a final rule on the 180-day exclusivity and that since the Citizens Petition describes a situation not addressed by FDA's current regulations, the case must be resolved by the statute. The FDA further noted in its ruling that "Mylan has not amended its patent certification as a result of the settlement." See FDA Ruling at 2. The FDA then concluded that it should treat Mylan's "IV Certification" as though it had been changed to a "III Certification." See FDA Ruling at 6. The FDA noted that the details of the Mylan-Pfizer settlement had not been made public but that FDA could, at least, recognize that Mylan "is no longer participating in litigation intended to prove that its product will not infringe the listed patent." See FDA Ruling at 6. Also, the FDA stated that although Mylan's ANDA had been approved "for more than a year, Mylan has never marketed its own ANDA product." See FDA Ruling at 6. Consequently, the FDA determined:

These facts lead FDA to presume that Mylan believes the product described in its ANDA may infringe the listed patent and is therefore waiting until patent expiring

before marketing its own product. The appropriate certification for a company that has chosen to wait until a listed patent expires before marketing is a paragraph III certification stating the date of the patent expiration.

(emphasis added). See FDA Ruling at 6.

Therefore, the FDA concluded that it considered Mylan's settlement of the Pfizer civil action and its marketing of Pfizer's product to have "effectively changed Mylan's certification from a paragraph IV to a paragraph III," thus rendering it no longer eligible for 180-day exclusivity.

Chayron counsels that the court must first determine whether Congress has directly spoken to the precise question at issue. If Congress' interest is clear, then the court, as well as the agency, must give effect to the "unambiguously expressed intent of Congress." If, however, the statute is silent or ambiguous with respect to a specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute. The statute, while complex, is not in this Court's opinion, ambiguous. It is, however, silent on the question of Congress' intent to permit or require the agency change a "IV certification" to a "III certification," particularly where it is based upon a party's "presumed" conduct.

Further, an agency in administering a program created by Congress, must be allowed to formulate policy and make rules to fill a "gap" which has been left, implicitly or explicitly, by Congress. There is an express delegation of authority to an agency

to fill by regulation a gap explicitly left open by Congress. However, in this Court's opinion, there is no explicit gap in the statute on the subject of the change of a "IV certification" to a "III certification," particularly when one considers the somewhat severe results such a change by agency ruling can effect. Where there is a Congressional delegation to an agency that is implicit instead of explicit, a court still may not substitute its construction of a statutory provision for a "reasonable interpretation made by the administrator of an agency." Chevron at 844.

While this Court fully recognizes the "considerable weight" that "should be accorded" to the FDA construction of the Hatch-Waxman Amendments, which it is entrusted to administer and the principle of deferral to administrative interpretations, Chevron, 467 U.S. at 844, this Court finds after a careful analysis of the FDA ruling of February 6, 2001 and the relevant statute, that the FDA's interpretation is an unreasonable one. First, there is no statutory provision which grants to the FDA, either expressly or implicitly, the authority to change a "IV certification" to a "III certification." Second, there is no FDA regulation that provides any basis for such a change. Third, the FDA ruling is based upon a presumption that is inadequately reached in this particular case. Finally, the sole precedent that the FDA relies upon, Mylan v. Henney, 94 F. Supp. 2d 36 (D.D.C. 2000), is clearly distinguishable because in that case Barr Laboratories, an ANDA applicant with a

"IV certification" by its own actions changed its "IV certification" to a "III certification" as part of its settlement with the NDA holder. In this case, Mylan has not effected a change to its certification and there is no evidence that its settlement agreement with Pfizer requires it to make such a certification change. The FDA ruling, at least on this subject, is therefore unreasonable, even if it possesses a right to make a ruling on this subject on a "case-by-case" basis. Therefore, there is, at least at this point, some likelihood of success by plaintiff Mylan on this feature of the FDA ruling.

2. FDA Ruling on the "First Commercial Marketing"

However, this does not end the analysis. The FDA also considered whether, even if Mylan were eligible for the 180-day exclusivity, that eligibility expired.

As noted by the FDA in its February 6, 2001 ruling, one of the ways that the 180-day exclusivity period can commence is that the Secretary receives notice from the applicant under the previous application of the "first commercial marketing" of the drug under the previous application. See 21 U.S.C. § 355(j)(5)(B)(iv). The FDA determined that Mylan's marketing of the Pfizer product following the settlement was "commercial marketing" that began the 180-day exclusivity period. The FDA explained its ruling:

whether Mylan markets the produce approved in its ANDA or the product approved in Pfizer's NDA is of little import to the statutory scheme; Mylan has begun commercial marketing of generic nifedipine, permitting Mylan to market nifedipine without triggering the beginning of

exclusivity would be inconsistent with the intent of the statutory scheme.

See FDA Ruling at 7-8.

Therefore, because more than 180 days had passed since March 28, 2000, the date the FDA determined Mylan began the commercial marketing, the exclusivity period had expired. At this point, this Court believes that the FDA's interpretation of the phrase "commercial marketing of the drug under the previous application" is a reasonable one. See Teva Pharmaceuticals USA, Inc. v. FDA, 182 F.3d 1003 (D.C. Cir. 1999). On the basis of this part of the FDA ruling, which this Court believes is a reasonable interpretation of the statute, Mylan must be deemed unlikely to succeed on the merits and, therefore, the defendants would prevail.

D. The Public Interest

This Court feels that the final factor, the public interest, must be resolved at this stage in favor of defendants and, therefore, in favor of denying injunctive relief to the plaintiff Mylan. Mylan's proposed interpretation of the "commercial marketing" prong of the FDA ruling would bring about a result that could well work against the main purpose of the Hatch-Waxman Amendments which is to "bring generic drugs onto the market as rapidly as possible." Mova Pharmaceutical Corp. v. Shalala, 140 F.3d at 1068 (D.C. Cir. 1998). The public interest favors promoting competition in the pharmaceutical industry which would, hopefully, have the desired effect of providing a market for affordable and attainable drugs.

V. Exhaustion of Remedies

On the eve of and during the February 16, 2001 hearing on the motion for injunctive relief, an issue arose as to the effect, if any, to be given to the fact that Mylan did not intervene, or otherwise participate, in the Citizens Petition filed by defendant Teva with the FDA. The Court requested briefing on this issue. Defendants Teva and Biovail then filed a motion to dismiss the complaint for failure by Mylan to exhaust its administrative remedies and a brief in support of that motion. Mylan filed a supplementary memorandum in support of its motion for preliminary injunction concerning the issues of exhaustion of remedies. The defendants, FDA, Thompson, and Schwetz, also filed a supplemental memorandum. While the FDA, Thompson and Schwetz do not contend that exhaustion of remedies with the FDA is a jurisdictional prerequisite of this case, they contend that Mylan's failure to avail itself of the opportunity to participate in the FDA proceeding is further grounds for denying injunctive relief.

This Court can find no related statute or regulation that requires Mylan as an "interested party" to submit any opposition to a Citizen Petition or be precluded from having standing to contest the final agency action of the FDA in this Court. Further, while the FDA might have been assisted by a filing by Mylan in the Teva Citizen Petition, the defendants have not presented satisfactory evidence to this Court that Mylan's failure to join those proceedings constituted bad faith sufficient, in itself, to

constitute a bar to injunctive relief. This Court has determined that, based on the other evidence presented at the hearing on Mylan's motion for injunctive relief, Mylan's motion must be denied. Consequently, the motion to dismiss of Teva and Biovail must be denied.

VI. Motion of Defendants Teva and Biovail
for Expedited Document Production by Mylan

Following the February 16, 2001 hearing on Mylan's motion for injunctive relief, defendants Teva and Biovail filed their First Request for Production of Documents seeking (1) a copy of the settlement agreement between Mylan and Pfizer; (2) any notes or correspondence between Mylan, Pfizer, Bayer AG and/or Bayer Corporation relating to the settlement agreement; (3) any documents concerning the obligation of Mylan, Pfizer and/or Bayer's right, obligation, privileges or interest after the dismissal of any claim in the Mylan-Pfizer-Bayer civil action; and (4) any marketing or licensing agreement or related notes or correspondence concerning Mylan's sale of Pfizer's Procardia® XL product or any related version of that product.

Teva and Biovail then moved, on February 21, 2001, for expedited production of the above documents because these documents bear directly on the factors to be considered by the Court in deciding whether to grant injunctive relief to Mylan. Mylan filed no response to this motion.

Because this Court believes that it has been able to sufficiently consider and decide the motion for injunctive relief

on the basis of the record presented by all parties to date and because this Court believes that the documents requested should be handled under the usual discovery procedures set forth under Federal Rule of Civil Procedure 34, the motion is DENIED.

VII. Conclusion

Accordingly, based upon the above findings of fact and conclusions of law, a preliminary injunction and temporary restraining order sought by Mylan pursuant to Federal Rule of Civil Procedure 65 is DENIED; defendants Teva and Biovail's motion to dismiss for failure by Mylan to exhaust its administrative remedies is DENIED and defendants Teva and Biovail's motion for expedited document production by Mylan is DENIED.

IT IS SO ORDERED.

The Clerk is directed to transmit copies of this order to counsel of record herein.

DATED: April 18, 2001


FREDERICK P. STAMP, JR.
UNITED STATES DISTRICT JUDGE